# Clinical Policy: Deferoxamine (Desferal)

Reference Number: LA.PHAR.146
Effective Date: 09.15.22
Last Review Date: 06.02.23~~08.22~~ Coding Implications
Line of Business: Medicaid Revision Log

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

****Please note: This policy is for medical benefit****

**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 ≥ 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** (must meet 1 or 2)**:**

1. ~~Refer to the off-label use policy if~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. ~~1.~~If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy 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 initial approval criteria;
2. Current documentation (within the last 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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.~~
~~**Approval duration: Duration of request or 6 months (whichever is less)**; or~~
1. ~~Refer to the off-label use policy if~~If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~):~~ ~~LA.PMN.53 for Medicaid.~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

**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 – LA.PMN.53 ~~for Medicaid, or evidence of coverage documents.~~;
**B.** Primary hemochromatosis;
**C.** Parkinson's disease.

**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~~.~~

*Appendix D: General Information*
- In FAIRPARK-II, deferiprone, an iron chelator, was associated with worse scores in measures of parkinsonism compared to placebo over a 36-week period in participants with newly diagnosed Parkinson's disease who had never received levodopa.

**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*<br>_____<br>**IM route if patient not in shock; IV infusion limited to patients in cardiovascular collapse.* | 6,000 mg/24 hr |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| 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<br>_____<br>**Average dose should not exceed 40 mg/kg/day until growth has ceased.* | 40 mg/kg/day (children)<br>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 tranfusional 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.
5. Devos D, Labreuche J, Rascol O, et al. Trial of deferiprone in Parkinson's disease. N Engl J Med 2022; 387:2045-2055.

## 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.

| HCPCS Codes | Description |
|---|---|
| J0895 | Injection, deferoxamine mesylate, 500 mg |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Converted corporate to local policy.Template changes applied to other diagnoses/indications and continued therapy section. | 09.22 | 09.15.22 |
| Template changes applied to other diagnoses/indications and continued therapy section.<br>Added Parkinson disease to section III with rationale in Appendix D. | 06.02.23 | |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Added verbiage this policy is for medical benefit only. | | |

**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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.