

## **Clinical Policy: Deferoxamine (Desferal)**

Reference Number: CP.PHAR.146

Effective Date: 11.01.15

Last Review Date: 08.22

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Deferoxamine (Desferal<sup>®</sup>) 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.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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 (must meet 1 or 2):**

1. 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 one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);

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. 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 one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
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) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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**

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) 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.

HCPCS Codes	Description
J0895	Injection, deferoxamine mesylate, 500 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policies combined for Centene Medicaid and Commercial (new) lines of business; no significant changes; age removed from acute iron intoxication and from chronic iron overload as can be used in patients younger than 3 in some cases; two gram vial removed; references reviewed and updated.	04.30.18	08.18
3Q 2019 annual review: no significant changes; added HIM-Medical Benefit line of business; references reviewed and updated.	05.14.19	08.19
3Q 2020 annual review: revised HIM-medical benefit to HIM line of business; references reviewed and updated.	04.20.20	08.20
3Q 2021 annual review: no significant changes; references for HIM line of business off-label use revised from HIM.PHAR.21 to HIM.PA.154; 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
Template changes applied to other diagnoses/indications and continued therapy section.	09.30.22	

**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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the 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.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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