Clinical Policy: Deferoxamine (Desferal)

Reference Number: CP.PHAR.146
Effective Date: 11.01.15
Last Review Date: 08.25
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®) is an iron-chelating agent.

FDA Approved Indication(s)

Desferal is indicated:

- As an adjunct to standard measures for the treatment of acute iron intoxication.
- For the treatment of transfusional iron overload in patients with chronic anemia.

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® that deferoxamine 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);
3. Serum ferritin level > 1,000 mcg/L;
4. If request is for brand Desferal, member must use generic deferoxamine, unless contraindicated or clinically significant adverse effects are experienced;

5. Therapy does not include concurrent use of other iron chelators, unless member has excess cardiac iron as evidence by mT2* ≤ 10 millisecond or iron-induced cardiomyopathy;
6. 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. Member is responding positively to therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline;
3. Current documentation (within the last 30 days) shows a serum ferritin level ≥ 500 mcg/L;
4. If request is for brand Desferal, member must use generic deferoxamine, unless contraindicated or clinically significant adverse effects are experienced;

5. Therapy does not include concurrent use of other iron chelators, unless member has excess cardiac iron as evidence by mT2* ≤ 10 millisecond or iron-induced cardiomyopathy;
6. 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;
C. Parkinson's disease.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
mT2*: myocardial T2

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 Q4-12 hr PRN* _____ **IM route if patient not in shock; IV infusion limited to patients in cardiovascular collapse.*	6,000 mg/24 hr
Chronic iron overload	Average daily dose between 20-60 mg/kg SC infusion QD	See dosing regimen
	20-40 mg/kg IV daily (children*) and 40-50 mg/kg IV daily (adults) for 5-7 days per week _____ **Maximum recommended daily dose is 40 mg/kg/day until growth (body weight and linear growth)has ceased.*	40 mg/kg/day (children) 60 mg/kg/day (adults)
	500-1,000 mg IM/day	1,000 mg/day

VI. Product Availability

Single-dose vial of lyophilized deferoxamine mesylate: 500 mg, 2 g

VII. References

1. Desferal Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022. Available at: https://www.novartis.com/us-en/sites/novartis_us/files/desferal.pdf. Accessed May 14, 2025.
2. Taher A, Musallam K, Cappellini MD. Guidelines for the management of non-transfusion dependent thalassaemia (NTDT) 2nd edition. Thalassaemia International Federation. 2018. Available at: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-clinical-management-of-non-transfusion-dependent-thalassaemias-updated-version/. Accessed May 14, 2025.
3. Taher A, Musallam K, Cappellini MD. Guidelines for the management of non-transfusion dependent β-thalassaemia 3rd edition. Thalassaemia International Federation. 2023. Available at: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-non-transfusion-dependent-%ce%b2-thalassaemia-3rd-edition-2023/. Accessed May 14, 2025.
4. Amid A, Lal A, Coates TD, Fucharoen S, et al. Guidelines for the management of α-thalassaemia. Thalassaemia International Federation. 2023. Available at: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-%ce%b1-thalassaemia/?-thalassaemia%2F. Accessed May 14, 2025.

5. 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 14, 2025.
6. Taher AT, Farmakis D, Forter JB, et al. TIF Guidelines for the management of transfusion-dependent β-thalassemia (TDT) 5th edition. Thalassaemia International Federation. 2025. Available at: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-transfusion-dependent-%CE%B2-thalassaemia-5th-edition-2025/. Accessed May 14, 2025.
7. 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	P&T Approval Date
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	
Added Parkinson disease to section III with rationale in Appendix D.	02.24.23	05.23
3Q 2023 annual review: updated FDA approved indications per prescribing information; per competitor analysis for continuation of therapy in chronic iron overload added requirement that member is responding positively to therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline; for chronic iron overload added requirement that therapy does not include concurrent use of other iron chelators, unless member has excess cardiac iron as evidence by cardiac T2* < 20 millisecond or iron-induced cardiomyopathy; references reviewed and updated.	04.14.23	08.23
3Q 2024 annual review: in Policy/Criteria, clarified policy is medically necessary for all deferoxamine products not only Desferal; references reviewed and updated.	05.23.24	08.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2025 annual review: for chronic iron overload, revised concurrent iron chelator bypass threshold from cardiac T2* < 20 ms to mT2* ≤ 10 ms per TIF guidelines; references reviewed and updated.	05.14.25	08.25

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.

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.