Clinical Policy: Deferoxamine (Desferal)

Reference Number: PA.CP.PHAR.146
Effective Date: 01/2018
Last Review Date: 07/2024

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
It is the policy of PA Health & Wellness 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 (must meet all):

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 cardiac T2* < 20 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: Refer to PA.CP.PMN.53

II. Continued Approval

A. Acute Iron Intoxication

1. Continuation of therapy will not be granted. New cases of acute iron intoxication must be evaluated against the initial approval criteria.

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA. PHARM.01) applies;
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 cardiac T2* < 20 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/day;
   b. IV: 40 mg/kg/day for children; 60 mg/kg/day for adults;
   c. IM: 1,000 mg/day.

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies; or
2. Refer to PA.CP.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 policies – PA.CP.PMN.53 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
pRBCs: packed red blood cells

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	1000 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	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 23, 2024.
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 22, 2024.
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 22, 2024.

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 22, 2024.
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 23, 2024.
6. 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
References reviewed and updated.	04/2018
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/2019
3Q 2020 annual review: references reviewed and updated.	07/2020
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021
3Q 2022 annual review: no significant changes; added criterion that member must use generic deferoxamine; references reviewed and updated.	07/2022
Added Parkinson disease to section III with rationale in Appendix D.	04/2023
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.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024