Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 08/01/2021**
Policy Number: PA.CP.PHAR.146	**Effective Date: 01/2020** **Revision Date: 07/2021**
Policy Name: Deferoxamine (Desferal)	

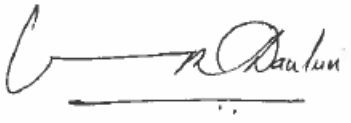
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

3Q 2021 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Deferoxamine (Desferal)

Reference Number: PA.CP.PHAR.146
Effective Date: 01/2018
Last Review Date: 07/2021

Coding Implications
Revision Log

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
It is the policy of health plans affiliated with Pennsylvania Health and Wellness 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. 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) and a serum ferritin level > 1,000 mcg/L;
3. 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Current documentation (within the last 30 days) shows a serum ferritin level ≥ 500 mcg/L;
3. 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. 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

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Acute iron intoxication	1000 mg x 1 dose, then 500 mg Q4 hr x 2 doses PRN, 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	1000-2000 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 _____ **Average dose should not exceed 40 mg/kg/day until growth has ceased.*	40 mg/kg/day (children) 60 mg/kg/day (adults)
	500-1,000 mg IM/day	1,000 mg/day

V. Product Availability

Vial of lyophilized deferoxamine mesylate: 500 mg

VI. References

1. Desferal Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed May 12, 2021.
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.

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	Approval Date
References reviewed and updated.	04.18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	

Reviews, Revisions, and Approvals	Date	Approval Date
3Q 2020 annual review: references reviewed and updated.	07/20	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	