Clinical Policy: Deferoxamine (Desferal)

Reference Number: PA.CP.PHAR.146
Effective Date: 01/18
Last Review Date: 11/16

Coding Implications
Revision Log

Description
The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness® clinical policy for deferoxamine mesylate (Desferal®).

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. Desferal will be used as an adjunct to standard measures used in treating acute iron intoxication (e.g., induction of emesis with syrup of ipecac; gastric lavage; suction and maintenance of a clear airway; control of shock with intravenous fluids, blood, oxygen, vasopressors; correction of acidosis);
3. Prescribed dose should not exceed 6000 mg in 24 hours given by intramuscular or intravenous administration;
4. Member has none of the following contraindications:
   a. Known hypersensitivity to the active substance in Desferal;
   b. Severe renal disease or anuria.

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. Documentation shows a transfusion history of ≥ 100 mL/kg of packed red blood cells (pRBCs) (e.g., ≥ 20 units of pRBCs for a 40 kg person or more in individuals weighing more than 40 kg) and a serum ferritin level > 1,000 mcg/L;
3. Member does not have primary hemochromatosis;
4. Member has none of the following contraindications:
   a. Known hypersensitivity to the active substance in Desferal;
   b. Severe renal disease or anuria.

Approval duration: 3 months

C. Other diagnoses/indications: Refer to PA.CP.PHAR.57 - Global Biopharm Policy.

II. Continued Approval

A. 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. Member does not have primary hemochromatosis;
4. Member has none of the following reasons to discontinue:
   a. Known hypersensitivity to the active substance in Desferal;
   b. Severe renal disease or anuria;
   c. Yersinia enterocolitica or Yersinia pseudotuberculosis infection, or mucormycosis.

Approval duration: 6 months

B. 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.PHAR.57 - Global Biopharm Policy**.**

Background

Description/Mechanism of Action:

Desferal, deferoxamine mesylate USP, is an iron-chelating agent, available in vials for intramuscular, subcutaneous, and intravenous administration. Desferal chelates iron by forming a stable complex that prevents the iron from entering into further chemical reactions. It readily chelates iron from ferritin and hemosiderin but not readily from transferrin; it does not combine with the iron from cytochromes and hemoglobin. Desferal does not cause any demonstrable increase in the excretion of electrolytes or trace metals. Theoretically, 100 parts by weight of Desferal is capable of binding approximately 8.5 parts by weight of ferric iron. Desferal is metabolized principally by plasma enzymes, but the pathways have not yet been defined. The chelate is readily soluble in water and passes easily through the kidney, giving the urine a characteristic reddish color. Some is also excreted in the feces via the bile.

Formulations:

Each carton of four vials contains either:
- 500 mg of sterile, lyophilized deferoxamine mesylate per vial; or
- 2 g of sterile, lyophilized deferoxamine mesylate per vial

FDA Approved Indications:

Desferal is an iron chelating agent/subcutaneous, intravenous or intramuscular formulation indicated for:
- Treatment of acute iron intoxication* and of chronic iron overload due to transfusion-dependent anemias.
  - Chronic iron overload:

- 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.

Limitations 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.

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Appendices

Appendix A: Abbreviation Key

pRBCs: packed red blood cells

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

1. Desferal Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2011. Available at https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/desferal.pdf. Accessed September 8, 2016.
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.