

Reference number(s)
1620-A

SPECIALTY GUIDELINE MANAGEMENT

DESFERAL (deferoxamine) deferoxamine mesylate (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- A. FDA-Approved Indication
Chronic iron overload due to transfusion-dependent anemias
- B. Compendial Uses
 - 1. Aluminum toxicity in patients undergoing dialysis
 - 2. Hereditary hemochromatosis

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chronic iron overload due to transfusion-dependent anemias:

- A. Initial requests: pretreatment serum ferritin level
- B. Continuation requests: current serum ferritin level

III. CRITERIA FOR INITIAL APPROVAL

- A. **Chronic Iron Overload due to Transfusion-Dependent Anemias**
Authorization of 6 months may be granted for treatment of chronic iron overload due to transfusion-dependent anemias when the pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
- B. **Aluminum toxicity in Members Undergoing Dialysis**
Authorization of 6 months may be granted for treatment of aluminum toxicity in members undergoing dialysis.
- C. **Hereditary Hemochromatosis**
Authorization of 6 months may be granted for treatment of hereditary hemochromatosis when phlebotomy is not an option (e.g., poor candidate due to underlying medical disorders) or the member had an unsatisfactory response to phlebotomy.

IV. CONTINUATION OF THERAPY

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Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when the following criteria are met:

A. Chronic Iron Overload due to Transfusion-Dependent Anemias

Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.

B. Aluminum toxicity in Members Undergoing Dialysis

Member is experiencing benefit from therapy as evidenced by any of the following:

1. Decreased serum aluminum concentrations
2. Symptomatic improvement (e.g., neurological symptom improvement, decreased bone pain)

C. Hereditary Hemochromatosis

Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.

V. REFERENCES

1. Desferal [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2020.
2. Deferoxamine mesylate [package insert]. Lake Forest, IL: Hospira, Inc.; August 2020.
3. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 7, 2020.
4. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed October 7, 2020.
5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: <http://www.clinicalpharmacology.com>. October 7, 2020.
6. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 3rd Edition [Internet]. *Thalassaemia International Federation* 2014;20:1-253.
7. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. *Blood* 2012;120(18):3657-69.
8. Adams P, Barton J, et al. How I Treat Hemochromatosis. *Blood* 2010; (116): 317-325.