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. <u>FDA-Approved Indication</u> Transfusional iron overload in patients with chronic anemia

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 Transfusional Iron Overload:

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

III. CRITERIA FOR INITIAL APPROVAL

A. Transfusional Iron Overload in Members with Chronic Anemia

Authorization of 6 months may be granted for treatment of transfusional iron overload in members with chronic anemia 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 venous access, poor candidate due to underlying medical disorders) or the member had an unsatisfactory response to phlebotomy.

IV. CONTINUATION OF THERAPY

A. Transfusional Iron Overload in Members with Chronic Anemia

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Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for transfusional iron overload with chronic anemia when 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

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for aluminum toxicity while undergoing dialysis when 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

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for hereditary hemochromatosis when member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.

V. REFERENCES

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- 5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: http://www.clinicalpharmacology.com. October 3, 2023.
- 6. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 4th Edition [Internet]. *Thalassaemia International Federation* 2021;20:1-351.
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- 8. Adams P, Barton J, et al. How I Treat Hemochromatosis. Blood 2010; (116): 317-325.
- 9. Kowdley KV, Brown KE, et al. ACG Clinical Guideline: Hereditary Hemochromatosis. *Am J Gastroenterol.* 2019;114(8):1202-1218.

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