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| Reference number(s) |
| 1621-A |

SPECIALTY GUIDELINE MANAGEMENT

FERRIPROX (deferiprone)

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.

FDA-Approved Indications

A. Transfusional Iron Overload due to Thalassemia Syndromes

1. Ferriprox oral solution is indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes.
2. Ferriprox tablets are indicated for treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes.

B. Transfusional Iron Overload due to Sickle Cell Disease or Other Anemias

1. Ferriprox oral solution is indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with sickle cell disease or other anemias.
2. Ferriprox tablets are indicated for treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with sickle cell disease or other anemias.

Limitations of Use

Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

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:

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

III. CRITERIA FOR INITIAL APPROVAL

Transfusional Iron Overload

Authorization of 6 months may be granted for treatment of transfusional iron overload when all of the following criteria are met:

- A. Transfusional iron overload is due to either of the following:
 1. Thalassemia syndromes
 2. Sickle cell disease or other anemias
- B. Member does not have transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia
- C. Pretreatment serum ferritin level is consistently greater than 1000 mcg/L.

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D. Dose of Ferriprox will not exceed 99 mg/kg per day.

IV. CONTINUATION OF THERAPY

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

- A. Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.
- B. Serum ferritin level is not consistently below 500 mcg/L.

V. REFERENCES

1. Ferriprox [package insert]. Rockville, MD: ApoPharma USA, Inc.; April 2021.
2. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed October 7, 2020.
3. 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.
4. 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.
5. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. *Blood* 2012;120(18):3657-69