Reference number(s)
1621-A

SPECIALTY GUIDELINE MANAGEMENT

FERRIPROX (deferiprone)
deferiprone (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 Indications
   1. **Transfusional Iron Overload due to Thalassemia Syndromes**
      a. Oral solution is indicated for treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes.
      b. Tablets are indicated for treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes.

   2. **Transfusional Iron Overload due to Sickle Cell Disease or Other Anemias**
      a. Ferriprox oral solution is indicated for treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with sickle cell disease or other anemias.
      b. 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.

B. Compendial Use
   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:
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
Authorization of 6 months may be granted for treatment of transfusional iron overload when all of the following criteria are met:
1. Transfusional iron overload is due to either of the following:

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a. Thalassemia syndromes
b. Sickle cell disease or other anemias

2. Member does not have transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia
3. Pretreatment serum ferritin level is consistently greater than 1000 mcg/L
4. Dose will not exceed 99 mg/kg per day

B. 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

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for transfusion iron overload when both of the following criteria are met:

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

B. 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

1. Ferriprox tablets [package insert]. Cary, NC: Chiesi USA, Inc.; July 2023.
2. Ferriprox oral solution [package insert]. Cary, NC: Chiesi USA, Inc.; November 2021.
3. Deferiprone [package insert]. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; November 2022.
4. Deferiprone [package insert]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; August 2023.
5. 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.
6. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. *Blood* 2012;120(18):3657-69.
7. Kowdley KV, Brown KE, et al. ACG Clinical Guideline: Hereditary Hemochromatosis. *Am J Gastroenterol*. 2019;114(8):1202-1218.
8. Porter J, Garbowski M. Consequences and management of iron overload in sickle cell disease. *Hematology Am Soc Hematol Educ Program*. 2013;2013:447-456.

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