Reference number(s)
1621-A

Specialty Guideline Management deferiprone-Ferriprox

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Ferriprox	deferiprone

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[1-3]

Transfusional Iron Overload due to Thalassemia Syndromes

- Oral solution is indicated for treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes.
- Tablets are indicated for treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes.

Transfusional Iron Overload due to Sickle Cell Disease or Other Anemias

- 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.
- 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.

Compendial Uses[7]

Hereditary hemochromatosis

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Transfusional iron overload:

- Initial requests: pretreatment serum ferritin level
- Continuation requests: current serum ferritin level

Coverage Criteria

Transfusional Iron Overload[1-6]

Authorization of 12 months may be granted for treatment of transfusional iron overload when all of the following criteria are met:

- Transfusional iron overload is due to either of the following:
  - Thalassemia syndromes
  - Sickle cell disease or other anemias
- Member does not have transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia.
- Pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
- Dose will not exceed 99 mg/kg per day.

Hereditary Hemochromatosis[7]

Authorization of 12 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.

Continuation of Therapy

Transfusional Iron Overload[1-3]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for transfusional iron overload when both of the following criteria are met:

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

Hereditary Hemochromatosis

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for hereditary hemochromatosis when the member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.

References

1. Ferriprox tablet [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.; January 2024.
4. Taher AT, Farmakis D, Porter JB, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 5th Edition [Internet]. Thalassaemia International Federation. 2025. Available at: https://thalassaemia.org.cy/publications/tif-publications/guidelines-for-the-management-of-transfusion-dependent-%ce%b2-thalassaemia-5th-edition-2025. Accessed January 30, 2025.
5. Shah FT, Porter JB, Sadasivam N, et al. Guidelines for the monitoring and management of iron overload in patients with haemoglobinopathies and rare anemias. Br J Haematol. 2022;196(2):336-350.
6. Coates TD, Wood JC. How we manage iron overload in sickle cell patients. Br J Haematol. 2017;177(5): 703-716.
7. Kowdley KV, Brown KE, et al. ACG Clinical Guideline: Hereditary Hemochromatosis. Am J Gastroenterol. 2019;114(8):1202-1218.