DEFERIPRONE

Generic	Brand	HICL	GCN	Exception/Other
DEFERIPRONE	FERRIPROX	18544		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the medication prescribed by or given in consultation with a hematologist or hematologist-oncologist?

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Does the patient have a diagnosis of transfusional iron overload due to a thalassemia syndrome?

   If yes, continue to #3.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Has the patient had a trial of Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Is the request due to intolerable toxicities, clinically significant adverse effects, or contraindication to current chelation therapy with Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine)?

   If yes, **approve for 6 months by HICL.**
   If no, continue to #5.

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INITIAL CRITERIA (CONTINUED)

5. Is the current chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) inadequate as defined by one of the following criteria?
   - Serum ferritin levels consistently above 2500mcg/L (at least 2 lab values in the previous 3 months)
   - The patient has evidence of cardiac iron accumulation (i.e., cardiac T2* MRI <10 milliseconds, iron induced cardiomyopathy, fall in left ventricular ejection fraction [LVEF], arrhythmia indicating inadequate chelation)

   If yes, **approve for 6 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **DEFERIPRONE (Ferriprox)** requires a diagnosis of transfusional iron overload due to a thalassemia syndrome. Treatment must be prescribed by or given in consultation with a hematologist or hematologist-oncologist. The following criteria must be also be met:
   - Trial of Exjade (deferasirox), Jadenu (deferasirox), or Desferal (deferoxamine) and the patient is experiencing one of the following:
     - Intolerable toxicities, clinically significant adverse effects, or contraindication to current chelation therapy with Exjade, Jadenu, or Desferal
     - Chelation therapy (i.e., Exjade [deferasirox], Jadenu [deferasirox], or Desferal [deferoxamine]) is inadequate defined by one of the following:
       - Serum ferritin levels consistently above 2500mcg/L (at least 2 lab values in the previous 3 months)
       - The patient has evidence of cardiac iron accumulation (i.e., cardiac T2* MRI <10 milliseconds, iron induced cardiomyopathy, fall in left ventricular ejection fraction [LVEF], arrhythmia indicating inadequate chelation)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of transfusional iron overload due to a thalassemia syndrome and meet the following criteria?
   - Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **DEFERIPRONE (Ferriprox)** requires a diagnosis of transfusional iron overload due to thalassemia syndromes for renewal. The following criteria must be met:

- Serum ferritin levels consistently greater than 500mcg/L (at least 2 lab values in the previous 3 months)

RATIONALE

Promote appropriate utilization of **DEFERIPRONE** based on FDA approved indication and treatment guidelines.

FDA APPROVED INDICATIONS

Ferriprox (deferiprone) is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

DOSAGE AND ADMINISTRATION

Ferriprox (deferiprone): 25mg/kg to 33mg/kg orally three times per day for a total daily dose of 75mg/kg to 99mg/kg per day. Consider interrupting therapy if serum ferritin level consistently falls below 500mcg/L.

AVAILABLE STRENGTHS

Ferriprox (deferiprone) is available in 500mg film coated tablets and 100mg/mL oral solution.

REFERENCES

- Ferriprox [Package Insert]. ApoPharma, Inc. Rockville, MD. February 2015.
- Standards of Care Guidelines for Thalassemia. 2012. Children's Hospital & Research Center, Oakland CA. Available from: http://thalassemia.com/documents/SOCGuidelines2012.pdf
- Cappellini MD, et al. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT): Iron Overload and Chelation. 3rd edition. Nicosia (CY):Thalassaemia International Federation;2014. Accessed 4/10/2017. Access here: http://www.resonancehealth.com/images/files/clinician-information/patient-management-guidelines/TIF%20Guidelines%20for%20the%20Management%20of%20Transfusion%20Dependent%20Thalassaemia.pdf
- Taher A, et al. Guidelines for the Management of Non Transfusion Dependent Thalassaemia (NTDT): Iron Overload and Chelation. Nicosia (CY):Thalassaemia International Federation;2013. Accessed 4/10/2017. Access here: http://thalassemia.com/documents/NTDT-TIF-guidelines.pdf

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DEFERIPRONE

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/17
Created: 08/17
Client Approval: 08/17
P&T Approval: 07/17