Reference number(s)
1622-A

SPECIALTY GUIDELINE MANAGEMENT

EXJADE (deferasirox; tablets for suspension)
JADENU (deferasirox; tablets, sprinkle granules)

deferasirox tablet for suspension
deferasirox tablet

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. Chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older
   2. Chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L

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:
A. Chronic Iron Overload due to Blood Transfusions (transfusional iron overload):
   1. Initial requests: pretreatment serum ferritin level
   2. Continuation requests: current serum ferritin level
B. Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes:
   1. Initial requests: pretreatment serum ferritin level and liver iron concentration
   2. Continuation requests: current serum ferritin level

III. CRITERIA FOR INITIAL APPROVAL

A. Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)
Authorization of 6 months may be granted for treatment of chronic iron overload due to blood transfusions when all of the following criteria are met:
   1. Pretreatment serum ferritin level is consistently greater than 1000 mcg/L.
   2. Dose of deferasirox tablet for suspension/Exjade will not exceed 40 mg/kg per day, dose of deferasirox/Jadenu will not exceed 28 mg/kg per day.
   3. Member's renal function has been evaluated.

B. Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes
Authorization of 6 months may be granted for treatment of chronic iron overload in members with non-transfusion dependent thalassemia syndromes when all of the following criteria are met:
1. Pretreatment serum ferritin level is greater than 300 mcg/L.
2. Pretreatment liver iron concentration (LIC) is at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
3. Dose of deferasirox tablet for suspension/Exjade will not exceed 20 mg/kg per day, dose of deferasirox/Jadenu will not exceed 14 mg/kg per day.
4. Member's renal function has been evaluated.

C. Hereditary Hemochromatosis
Authorization of 6 months may be granted for treatment of hereditary hemochromatosis when both of the following criteria are met:
1. 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.
2. Member's renal function has been evaluated.

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 the following criteria are met:

A. Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)
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.
3. Member's renal function has been evaluated.

B. Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes
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 300 mcg/L.
3. Member's renal function has been evaluated.

C. Hereditary Hemochromatosis
1. Member is experiencing benefit from therapy as evidenced by a decrease in serum ferritin levels as compared to pretreatment baseline.
2. Member's renal function has been evaluated.

V. REFERENCES

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4. 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 1, 2020.
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8. Taher A, Musallam K, Cappellini M, et al. Guidelines for the management of non-transfusion dependent thalassaemia (NTDT) 2nd Edition. *Thalassaemia International Federation* 2018;1-117.
9. Phatak P, Brissot P, Bonkovsky H et al. A phase I/II, open-label, dose-escalation trial of once daily oral chelator deferasirox to treat iron overload in HFE-related hereditary hemochromatosis: Final Results of the Core Study. *Blood* 2009;114: 1514.
10. Adams P, Barton J, et al. How I Treat Hemochromatosis. *Blood* 2010;(116): 317-325.
11. Deferasirox tablet for suspension [package insert]. North Wales, PA: Actavis Pharma, Inc; January 2020.
12. Deferasirox tablet [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; June 2020.