Reference number(s)
1622-A

SPECIALTY GUIDELINE MANAGEMENT

EXJADE (deferasirox)
JADENU (deferasirox)
deferasirox (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. 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 or liver iron concentration (where applicable).
   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 both 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.

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 both of the following criteria are met:

1. Member meets any of the following:
   a. Pretreatment serum ferritin level is greater than or equal to 800 mcg/L.
   b. Pretreatment liver iron concentration (LIC) is at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw).
   c. Pretreatment serum ferritin level is greater than 300 mcg/L to less than 800 mcg/L and has clinical or laboratory measures indicative of iron overload (e.g., liver disease, renal disease).
2. 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.

C. 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. Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for chronic iron overload due to blood transfusions (transfusional 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. Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes
Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for chronic iron overload with non-transfusion dependent thalassemia syndrome 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 300 mcg/L.

C. 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. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
3. Deferasirox tablet for suspension [package insert]. North Wales, PA: Actavis Pharma, Inc; August 2021.
4. Deferasirox tablet [package insert]. Princeton, NJ: Dr. Reddy's Laboratories Inc.; January 2021.
5. Deferasirox granule [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; September 2022.
6. 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.
7. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. Blood 2012;120(18):3657-69.
8. Taher A, Musallam K, Cappellini M, et al. Guidelines for the management of non-transfusion dependent β-thalassaemia 3rd Edition. Thalassaemia International Federation 2023;1-132.

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. Kowdley KV, Brown KE, et al. ACG Clinical Guideline: Hereditary Hemochromatosis. *Am J Gastroenterol*. 2019;114(8):1202-1218.