deferasirox (Exjade®, Jadenu®); deferiprone (Ferriprox®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO017

Description

Deferasirox (Exjade, Jadenu), and deferiprone (Ferriprox) are orally administered iron chelating agents.

Length of Authorization

- Initial: Three months
- Renewal: Six months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
deferasirox (generic Exjade)	125 mg tablet for suspension	Hemosiderosis (chronic iron overload) – non-transfusion related thalassemia syndrome Hemosiderosis (chronic iron overload) – transfusion thalassemia	Non-transfusion thalassemia syndrome: Monthly quantity to allow for a maximum of 20 mg/kg per day Setting of transfusions: Monthly quantity to allow for a maximum of 40 mg/kg per day
	250 mg tablet for suspension		
	500 mg tablet for suspension		
deferasirox (Exjade)	125 mg tablet for suspension		
	250 mg tablet for suspension		
	500 mg tablet for suspension		
defirasirox (generic Jadenu)	90 mg tablet	Hemosiderosis (chronic iron overload) – non-transfusion related thalassemia syndrome Hemosiderosis (chronic iron overload) – transfusion thalassemia	Non-transfusion thalassemia syndrome: Monthly quantity to allow for a maximum of 14 mg/kg per day Setting of transfusions: Monthly quantity to allow for a maximum of 28 mg/kg per day
	180 mg tablet		
	360 mg tablet		
deferasirox (Jadenu)	90 mg tablet		
	180 mg tablet		
	360 mg tablet		
	90 mg granule (sprinkle)		

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	180 mg granule (sprinkle)		
	360 mg granule (sprinkle)		
deferiprone (Ferriprox)	100 mg/1 mL solution	Hemosiderosis (chronic iron overload) – transfusion thalassemia	Monthly quantity to allow for a maximum of 99 mg/kg per day
	500 mg tablet		
	1000 mg tablet		

Initial Evaluation

I. Deferasirox (Exjade, Jadenu), and deferiprone (Ferriprox) may be considered medically necessary when the following criteria below are met:
   A. Prescribed by, or in consultation with, a specialist (e.g., hematologist); **AND**
   B. Documentation of the members weight that has been measured in the past three months; **AND**
   C. A diagnosis of one of the following:
      1. **Chronic iron overload due to <u>non-transfusion</u> dependent thalassemia syndromes**; **AND**
         i. Member is ten years of age or older; **AND**
         ii. Documentation of a liver iron (Fe) concentration (LIC) of at least 5 mg per gram of dry weight; **AND**
         iii. Documentation serum ferritin levels are greater than 300 mcg/L; **AND**
         iv. Generic deferasirox (generic for Exjade OR Jadenu) has been prescribed; **OR**
            a. Brand Exjade or Jadenu is prescribed and **<u>both</u>** generic deferasirox (generic for Exjade) AND deferasirox (generic for Jadenu) have been ineffective or contraindicated (disliking taste of the tablet suspension is not considered for inefficacy or contraindication) (deferiprone [Ferriprox] is not FDA-approved for this indication); **OR**
      2. **Chronic iron overload due to <u>blood transfusions</u>**; **AND**
         i. Member is two years of age or older if brand or generic deferasirox (Exjade) or deferasirox (Jadenu) are prescribed; **OR**

a. Member is 18 years of age or older if deferiprone (Ferriprox) is prescribed; **AND**

ii. Documentation is provided that the member has received transfusions that have resulted in consistent serum ferritin level greater than 1000 mcg/L; **AND**

iii. Generic deferasirox (generic for Exjade OR Jadenu) has been prescribed; **OR**

a. Brand Exjade, Jadenu, or deferiprone (Ferriprox) is prescribed and **both** generic deferasirox (generic for Exjade) AND deferasirox (generic for Jadenu) have been ineffective or contraindicated (disliking taste of the tablet suspension is not considered for inefficacy or contraindication)

II. Deferasirox (Exjade), deferasirox (Jadenu) and deferiprone (Ferriprox) are considered not medically necessary when criteria above are not met and/or when used for:
A. Plasmodium falciparum parasitemia

III. Deferasirox (Exjade), deferasirox (Jadenu) and deferiprone (Ferriprox) are considered investigational when used for all other conditions, including but not limited to:
A. Hereditary hemochromatosis
B. Porphyria cutanea tarda

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; AND
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; AND
III. Prescribed by, or in consultation with, a specialist (e.g., hematologist); **AND**
IV. Documentation of the members weight that has been measured in the past three months; **AND**
A. **Chronic iron overload due to non-transfusion dependent thalassemia syndromes**; **AND**
1. Documentation of a serum ferritin levels are greater than 300 mcg/L; **AND**
2. Generic deferasirox (generic for Exjade OR Jadenu) has been prescribed ; **OR**
i. Brand Exjade or Jadenu is prescribed and **both** generic deferasirox (generic for Exjade) AND generic deferasirox (generic for Jadenu) have been

ineffective or contraindicated (disliking taste of the tablet suspension is not considered for inefficacy or contraindication) (deferiprone [Ferriprox] is not FDA-approved for this indication); **AND**

3. A response to treatment, defined by a decline in serum ferritin level, has been documented; **OR**

B. **Chronic iron overload due to <u>blood transfusions</u>; AND**
   a. Documentation that the member is continuing to receive transfusions resulting in serum ferritin levels consistently greater than 500 mcg/L; **AND**
   b. Generic deferasirox (generic for Exjade OR Jadenu) has been prescribed; **OR**
      i. Brand Exjade, Jadenu, or deferiprone (Ferriprox) is prescribed and **<u>both</u>** generic deferasirox (generic for Exjade) AND generic deferasirox (generic for Jadenu) have been ineffective or contraindicated (dislike taste of the tablet suspension is not considered for inefficacy or contraindication); **AND**
   c. A response to treatment, defined by a decline in serum ferritin level, has been documented

Supporting Evidence

I. The agents listed in this policy are iron chelating agents indicated for chronic iron overload, but have not been shown to improve survival or disease-related symptoms. Of note, the products are not interchangeable on a dose basis. Deferiprone (Ferriprox) is an iron chelator indicated only for transfusional iron overload when other chelation therapy has been inadequate.
II. Per the package inserts for the medications listed in this policy, doses are based on weight. Safety and efficacy of the medications have been studied for FDA-approved weight based doses. Doses escalation beyond these limits has not been evaluated.
III. Clinical trials evaluated deferasirox (Exjade) and deferasirox (Jadenu) in patients 10 years of age or older for chronic iron overload due to non-transfusion dependent thalassemias, and for two years of age an older for iron overload due to blood transfusions. Deferiprone (Ferriprox) has not been evaluated for safety and efficacy in patients younger than 18 years of age.
IV. For iron overload not due to transfusion, deferasirox (Exjade) and deferasirox (Jadenu) were studied in patients with an LIC of at least 5 mg of iron per dry weight and a serum ferritin greater than 300 mcg/L. Levels of serum ferritin below 300 mcg/L are considered within normal range and would not meet medical necessity for dosing of iron overload treatment products.
V. For transfusion related iron overload, patient with a serum ferritin level greater than or equal to 1000 mcg/L will be considered for iron overload products. Upon renewal, patients with a serum ferritin level below 500 mcg/L will have therapy temporarily discontinued.
VI. As of December 2019, AB-rated generics for Exjade and Jadenu tablets were available on the market.

Investigational or Not Medically Necessary Uses

I. Plasmodium falciparum parasitemia
   A. In a prospective, double-blind, placebo-controlled trial, deferiprone was found to be clinically ineffective against plasmodium falciparum parasitemia.
II. Hereditary hemochromatosis and porphyria cutanea tarda
   A. Clinical trials are investigating iron overload agents in these settings.

References

1. Exjade [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May, 2018.
2. Jadenu [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May, 2018.
3. Ferriprox [Prescribing Information]. Toronto, Ontario, Canada. Apotex Inc. February, 2015.
4. Cohen AR, Glimm E, Porter JB. Effect of transfusional iron intake on response to chelation therapy in beta-thalassemia major. Blood. 2008;111(2):583-7.
5. Taher AT, Porter JB, Viprakasit V, et al. Deferasirox demonstrates a dose-dependent reduction in liver iron concentration and consistent efficacy across subgroups of non-transfusion-dependent thalassemia patients. Am J Hematol. 2013;88(6):503-6.
6. Vichinsky E, Onyekwere O, Porter J, et al. A randomised comparison of deferasirox versus deferoxamine for the treatment of transfusional iron overload in sickle cell disease. Br J Haematol. 2007;136(3):501-8.
7. Tricta F, Uetrecht J, Galanello R, et al. Deferiprone-induced agranulocytosis: 20 years of clinical observations. Am J Hematol. 2016;91(10):1026-31.

Policy Implementation/Update:

Date Created	May 2019
Date Effective	May 2019
Last Updated	December 2019
Last Reviewed	08/2013, 05/2019, 12/2019

Action and Summary of Changes	Date
Addition of generic Jadenu and new strength of deferiprone to the policy, with requirement to have trial and failure or contraindication, to both generic Exjade and Jadenu prior to payment consideration for brand products of this policy.	12/2019
Iron chelating agent policies combined, criteria added in regards to the following: weight documentation, ferritin level documentation, addition of a policy to Jadenu, specialist prescribing, additional of generic deferasirox (Exjade) tablet for oral suspension and step through this product. Transition to policy format.	05/2019