BlueCross BlueShield
Federal Employee Program

EXJADE (**deferasirox**) tablets, for oral suspension
JADENU (**deferasirox**) tablets, for oral use
JADENU SPRINKLE (**deferasirox**) granules, for oral use

Preferred product: generic deferasirox

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload. Exjade and Jadenu are used for the treatment of patients who have too much iron in their blood due to repeated blood transfusions or for patients with an inherited disorder called non-transfusion-dependent thalassemia (NTDT). Too much iron in the blood results in the formation of insoluble ferritin which over time can lead to organ damage. Although NTDT usually does not require individuals to get frequent red blood cell transfusions, some patients with NTDT are still at risk for iron overload that can lead to organ damage (1-2).

Regulatory Status

FDA-approved indications: Exjade and Jadenu are iron chelators indicated for:

1. Treatment of chronic iron overload due to blood transfusions in patients 2 years of age and older. This indication is based on reduction in serum ferritin and liver iron concentration (LIC).
2. Treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight and a serum ferritin greater than 300 mcg/L (1-2).

Limitations of Use: The safety and effectiveness of Exjade and Jadenu when administered with other iron chelation therapy have not been established (1-2).

Exjade and Jadenu have a boxed warning regarding the development of renal failure, hepatic failure and gastrointestinal hemorrhage, which can be fatal in some patients. Creatinine clearance (estimated by the Cockcroft-Gault method) must be determined before initiating therapy in all patients in order to establish a reliable pretreatment baseline. Monitor serum creatinine weekly during the first month after initiation or modification of therapy and at least monthly thereafter (1-2).

Exjade and Jadenu are contraindicated in patients with creatinine clearance less than 40 mL/min or serum creatinine greater than 2 times the age-appropriate upper limit of normal. Baseline serum transaminases and bilirubin should also be obtained in all patients before the initiation of treatment

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and every 2 weeks during the first month and at least monthly thereafter (1-2).

Avoid the use of Exjade and Jadenu in patients with severe (Child-Pugh C) hepatic impairment. Patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment may be at higher risk for hepatic toxicity. Closely monitor patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment for efficacy and adverse reactions that may require dose titration (1-2).

GI hemorrhage, including deaths, has been reported, especially in elderly patients who had advanced hematologic malignancies and/or low platelet counts. Non-fatal upper GI irritation, ulceration and hemorrhage have been reported in patients, including children and adolescents, receiving Exjade or Jadenu. Patients should be monitored for suspected GI ulceration or hemorrhage during Exjade or Jadenu therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. The risk of gastrointestinal hemorrhage may be increased when administering Exjade or Jadenu in combination with drugs that have ulcerogenic or hemorrhagic potential, such as non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, oral bisphosphonates, or anticoagulants (1,2).

Exjade and Jadenu are contraindicated in patients with any of the following: serum creatinine greater than 2 times the age-appropriate upper limit of normal, creatinine clearance less than 40 mL/min, high-risk myelodysplastic syndromes (MDS), advanced malignancies and platelet counts below 50,000 per microliters (1-2).

Summary

Exjade (deferasirox) and Jadenu (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload. Exjade and Jadenu are FDA approved for treating chronic iron overload due to blood transfusions in patients 2 years of age and older. This orally active iron chelator is most commonly used in patients with b-thalassemia, who, with repeated red blood cell transfusions, accumulate iron. Exjade and Jadenu is also approved to treat patients 10 years of age and older who have chronic iron overload resulting from a genetic blood disorder called non-transfusion-dependent thalassemia (NTDT) (1-2).

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Exjade and Jadenu while maintaining optimal therapeutic outcomes.

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.