Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

JADENU® and JADENU® SPRINKLE (*deferasirox*) PA CRITERIA:

JADENU® is indicated for:

- Treatment of chronic iron overload due to a blood transfusion in patients age ≥ 2 years. Therapy with JADENU® should be started when a patient has evidence of chronic iron overload, such as the transfusion of approximately 100 mL/kg of packed red blood cells (approximately 20 units for a 40-kg patient) and a serum ferritin consistently >1000 mcg/L.
- Treatment of chronic iron overload in patients ≥ 10 years with non-transfusion-dependent thalassemia syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (dw) and a serum ferritin greater than 300 mcg/L. This indication is based on achievement of an LIC less than 5 mg Fe/g dw.

Prior authorization is required for JADENU®**.** PA approval will be considered when the following criteria are met.

Initial Authorization: 6 Months **OR** 12 Months with documentation of EXJADE® intolerability

1. The patient must meet the minimum age and weight requirements recommended by the package insert for FDA approved indication; **AND**
2. The prescribed dose does not exceed the FDA approved dose; **AND**
3. The medication is prescribed by or in consultation with a hematologist and/or hepatologist; **AND**
4. The patient does not have a contraindication to JADENU®; **AND**
5. The patient has a diagnosis of chronic iron overload due to blood transfusions and a serum ferritin >1000 mcg/L on two lab values at least one month apart; **AND**
    a. Documented history of failure with EXJADE® (deferasirox) defined as:
        i. Trial of EXJADE® ≥ 6 months and serum ferritin levels do not show improvement; **OR**
        ii. Documentation of prolonged fevers requiring hospitalization while on EXJADE®; **OR**
        iii. Documentation of tissue iron concentrations and prior treatment with EXJADE®:
            1. Liver T2* MRI ≤ 6.3 ms or Cardiac T2* MRI ≤ 20 ms; **OR**
            2. Atomic absorption spectrophotometry (AAS); HIC ≥ 99 micromol/g dw

    OR

    b. Documented history of lactose intolerance diarrhea.

OR

6. The patient has a diagnosis of non-transfusion dependent thalassemia syndromes with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (dw) and a serum ferritin greater > 300 mcg/L; **AND**
    - **a.** Documentation of iron overload related to anemia or recent history of blood transfusions resulting in chronic iron overload (found in patient's medical conditions, progress notes, and/or discharge notes**; OR**
    - b. Documentation of tissue iron concentrations and prior treatment with EXJADE®; **AND**
        - i. Liver T2* MRI ≤ 6.3 ms or Cardiac T2* MRI ≤ 20 ms; **OR**
        - ii. Atomic absorption spectrophotometry (AAS); hepatic iron concentration (HIC) ≥ 70 micromol/g dw.

Re-Authorization: 12 Months

1. Patient continues to meet initial authorization criteria; **AND**
2. The prescribed dose does not exceed the FDA-approved dose; **AND**
3. Documentation of serum ferritin level around 500 mcg/L or higher; **AND**
4. Documentation of a positive clinical response to JADENU® as defined by:
    a. A reduction, from baseline, in serum ferritin level or tissue iron concentrations; **OR**
    b. Maintaining a stable serum ferritin level with previous history of increasing serum ferritin levels.

JADENU® Dosing: Please refer to the package insert for dosing.

Formulation: JADENU® is available as 90 mg, 180 mg and 360 mg oral tablets or granules

Notes:

- A normal **cardiac T2* MRI** is > 20 ms. Iron overload can be classified as follows:
    - Cardiac T2* MRI < 20 ms indicates presence of mild to moderate cardiac iron overload
    - Cardiac T2* MRI <10 ms indicates severe myocardial iron overload
- A normal **liver T2* MRI** is > 6.3 ms. Iron overload can be classified as follows:
    - A liver T2* MRI 2.7-6.3 ms indicates the presence of mild liver iron overload
    - A liver T2* MRI 1.4-2.7 ms indicates the presence of moderate liver iron overload
    - A liver T2* MRI <1.4 ms indicates severe hepatic iron overload
- Normal **HIC** ranges from 10-35 micromol/g dw. The preferred method for measuring iron overload is atomic absorption spectrophotometry (AAS):
    - Mild = HIC 70-98 micromol/g dw
    - Moderate = HIC 99-200 micromol/g dw
    - Severe = HIC ≥ 200 micromol/g dw