Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

JADENU® (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.

Initial Authorization: 6 months at a time OR 12 months with documentation of EXJADE® intolerability (fever, lactose intolerance diarrhea)

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label

AND

☐ Yes ☐ No Prescribed by *or in consultation* with a hematologist and/or hepatologist

AND

☐ Yes ☐ No Patient must not have a contraindication to JADENU® [a]

AND

- **One of the following:** ☐ Yes ☐ No Patient have chronic iron overload due to blood transfusions and a serum ferritin >1000 mcg/L on two lab values at least one month apart

  AND

  ☐ Yes ☐ No Documented history of failure with EXJADE® (deferasirox) [b]

  OR

- ☐ Yes ☐ No Documentation of lactose intolerance diarrhea

OR

☐ Yes ☐ No Patients have 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

- 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

- Documentation tissue iron concentrations and prior treatment with EXJADE®.
  - Liver T2* MRI ≤ 6.3 ms[c] or Cardiac T2* MRI ≤ 20 ms[d]

    OR

  - Atomic absorption spectrophotometry (AAS); hepatic iron concentration (HIC) ≥ 70 micromol/g dw[e]

Re-authorization for JADENU® 12 months based on the following criteria[1]

- ☐ Yes ☐ No Documentation of serum ferritin level around 500 mcg/L or higher
  AND
- ☐ Yes ☐ No Documentation of a positive clinical response to JADENU® as defined by:
  - A reduction, from baseline, in serum ferritin level or tissue iron concentrations
    OR
  - Maintaining a stable serum ferritin level with previous history of increasing serum ferritin levels

[a] **CONTRAINDICATIONS:**

- Estimated GFR less than 40 mL/min/1/73 m^2S
- Patients with poor performance status
- Patients with high-risk myelodysplastic syndromes (MDS)
- Patients with advanced malignancies.
- Patients with platelet counts < 50 x 10^9/L
- Known hypersensitivity to JADENU® (deferasirox) or any component of JADENU®

[b] **DOCUMENTATION OF EXJADE FAILURE**[2]

- Trial of EXJADE® ≥ 6 months and serum ferritin levels do not show improvement
  OR
- Documentation of prolonged fevers requiring hospitalization while on EXJADE®
  OR
- Documentation of tissue iron concentrations and prior treatment with EXJADE®
  - Liver T2* MRI ≤ 6.3 ms[c] or Cardiac T2* MRI ≤ 20 ms[d]
    OR
  - Atomic absorption spectrophotometry (AAS); HIC ≥ 99 micromol/g dw[e]

NOTE:

[c]A normal cardiac T2* MRI is > 20 ms. Iron overload can be classified as follows[3]:

- A cardiac T2* MRI < 20 ms indicates the presence of mild to moderate cardiac iron overload
- A cardiac T2* MRI <10 ms indicates severe myocardial iron overload

[d]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

[e]Normal HIC ranges from 10-35 micromol/g dw. The preferred method for measuring iron overload is atomic absorption spectrophotometry (AAS)[4]:

- Mild = HIC 70-98 micromol/g dw
- Moderate = HIC 99-200 micromol/g dw
- Severe = HIC ≥ 200 micromol/g dw

References:

1. JADENU® prescribing information, May,2019. Novartis Pharmaceuticals, Inc.
2. EXJADE® prescribing information, May, 2018. Novartis Pharmaceuticals, Inc.
3. Schrier, S. Bacon, B. Approach to the Patient with Suspected iron Overload. Wolters Kluwer Health (Up-To-Date). [updated 2016 Feb 23; accessed 2016 Mar 22].
4. Adams P, Brissot P, Powell LW. EASL International Consensus Conference on Haemochromatosis. [accessed 2016 Mar 22] J Hepatol 2000; 33: 485.