Manual Prior Authorization

MISSISSIPPI DIVISION OF MEDICAID

JADENU® (deferasirox) PA Criteria

Initial Authorization: PA approved for 6 months at a time or 12 months with documentation of EXJADE® intolerability (fever, lactose intolerance diarrhea).
☐ Yes ☐ No—Patients must be age ≥ 2 years and in need of treatment of chronic iron overload due to blood transfusions. 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 microgram (mcg)/L.

- Patient must not have a contraindication to JADENU®[a]
  AND
- Prescribed by *or in consultation* with a hematologist and/or hepatologist
  AND
- Patients must be ≥ 2 years of age (chronic iron overload due to blood transfusions) and a serum ferritin >1000 mcg/L on two lab values at least one month apart
  AND
  - Documented history of failure with EXJADE (defarasirox)®[b]
    OR
  - Documentation of lactose intolerance diarrhea

OR

☐ Yes ☐ No Patients must be ≥10 years of age 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 > 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 or Cardiac T2* MRI ≤ 20 ms
    OR
  - Atomic absorption spectrophotometry (AAS); hepatic iron concentration (HIC) ≥ 70 micromol/g dw

Re-authorization for JADENU® [1] will be for 12 months

- ☐ 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

Instructions/Information

[a] **CONTRAINDICATIONS:**

- Serum Cr > 2x the age-appropriate upper limit of normal or CrCl of < 40 mL/min
- Patients with poor performance status
- Patients with high-risk myelodysplastic syndromes (MDS)
- Patients with advanced malignancies
- Patients with platelet counts < 50 x 10 /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 or Cardiac T2* MRI ≤ 20 ms
    OR
  - Atomic absorption spectrophotometry (AAS); HIC ≥ 99 micromol/g dw

NOTE:

JADENU® (defarasirox) 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 (at least 20 units for a 40-kg patient or more) and a serum ferritin consistently >1000 mcg/L.
- Treatment of chronic iron overload in patients 10 years of age and older 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.

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

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)[4]:

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

References:

1. JADENU prescribing information, Oct 2015. Novartis Pharmaceuticals, Inc.
2. EXJADE prescribing information, July 2015.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.