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®

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)

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 or Cardiac T2* MRI ≤ 20 ms

    OR

    ▪ Atomic absorption spectrophotometry (AAS); hepatic iron concentration (HIC) ≥ 70 micromol/g dw
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

**CONTRAINDICATIONS:**
- Estimated GFR less than 40 mL/min/1.73 m\(^2\)
- 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®

**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:**
- 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 dw
References:
1. JADENU® prescribing information, May, 2019. Novartis Pharmaceuticals, Inc.
2. EXJADE® prescribing information, May, 2018. Novartis Pharmaceuticals, Inc.