

Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's
	Prior Authorization Criteria
Original Development Date: Original Effective Date:	May 29, 2015
Revision Date:	March 10, 2020, March 31, 2020, October 15, 2021

# JADENU<sup>®</sup> (deferasirox)

TYPE OF IRON OVERLOAD	LENGTH OF AUTHORIZATION
Transfusional/Non-Transfusional	Up to 1 year

# REVIEW CRITERIA:

## **Transfusional Iron Overload initiation of Therapy:**

- 1. Patient must be  $\geq 2$  years of age on the date of request for Jadenu with chronic iron overload due to blood transfusions.
- 2. Documentation of iron overload related to anemia found in patient's medical conditions, progress notes, and/or discharge notes.
- 3. Documentation in medical records (e.g., progress notes, discharge notes. . .) of a recent history of frequent blood transfusions that has resulted in chronic iron overload.
- 4. Documentation in medical records (*eg. progress notes, discharge notes*. . .) of <u>failure of Exjade</u> (after a minimum of <u>3 months of therapy</u>) as demonstrated by serum ferritin must be consistently >1000 mcg/L despite maximization of Exjade dosage of 40mg/kg/day. (Lab results submitted should be dated within the past month.)
- 5. Starting dose is 14 mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

#### **Transfusional Iron Overload continuation of therapy:**

- 1. Ferritin levels must be >500mcg/L.
- 2. Dose must not exceed 28mg/kg/day.
- 3. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

#### Non-Transfusional Iron Overload initiation of therapy:

- 1. Patient must be  $\geq 10$  years of age on the date of request for Jadenu with non-transfusion-dependent thalassemia.
- 2. Documentation of iron overload related to anemia found in patient's medical conditions, progress notes, and/or discharge notes.
- 3. Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of initiation (copy lab results must be submitted).



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- 4. Documentation in medical records (*eg. progress notes, discharge notes*. . .) of <u>failure of Exjade</u> (after a minimum of <u>3 months of therapy</u>) as demonstrated by serum ferritin must be consistently >300 mcg/L despite maximization of Exjade dosage of 40mg/kg/day. (Lab results submitted should be dated within the past month.)
- 5. Liver iron concentration (LIC) must be  $\geq$ 5 mg Fe/g dried weight (dw)
- 6. Starting dose is 7mg/kg/day. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).

## Non-Transfusional Iron Overload continuation of therapy:

- 1. Serum ferritin levels must be >300mcg/L.
- 2. Liver iron concentration (LIC) must be  $\geq 3$  mg Fe/g dw.
- 3. Dose must not exceed: 14mg/kg/day.
- 4. Calculate dose to the nearest whole tablet (90 mg, 180 mg, or 360 mg).