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| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
| Original Development Date: Original Effective Date: Revision Date: | November 13, 2008 February 7, 2013; April 3, 2013; March 30, 2015 |

EXJADE® (deferasirox)

| TYPE OF IRON OVERLOAD | LENGTH OF AUTHORIZATION |
|---------------------------------|-------------------------|
| Transfusional/Non-Transfusional | Up to 3 months |

REVIEW CRITERIA:

Transfusional Iron Overload initiation of Therapy:

1. Patient must be ≥ 2 years of age on the date of request for Exjade.
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. Serum ferritin must be consistently >1000 mcg/L. (Lab results submitted should be dated within the past month.)
5. Starting dose must not exceed 20mg/kg/day. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.

Transfusional Iron Overload continuation of therapy:

1. Serum ferritin must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
2. Ferritin levels must be >500 mcg/L.
3. Dose must not exceed 40mg/kg/day.
4. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.

Non-Transfusional Iron Overload initiation of therapy:

1. Patient must be ≥ 10 years of age on the date of request for Exjade.
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).
4. Serum ferritin levels must be >300 mcg/L.
5. Liver iron concentration (LIC) must be ≥ 5 mg Fe/g dried weight (dw)



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6. Dose must not exceed: 10mg/kg/day (**if LIC is ≤ 15 mg Fe/g dw**).
20mg/kg/day (**if LIC is > 15 mg Fe/g dw**)
7. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.

Non-Transfusional Iron Overload continuation of therapy:

1. Serum ferritin and liver iron concentration (LIC) must have been measured within 30 days of continuation of therapy request (copy lab results must be submitted).
2. Serum ferritin levels must be >300 mcg/L.
3. Liver iron concentration (LIC) must be ≥ 3 mg Fe/g dw.
4. Dose must not exceed: 10mg/kg/day (**if LIC is 3 – 7 mg FE/g dw**)
20mg/kg/day (**if LIC is >7 mg FE/g dw**)
5. Calculate dose to the nearest whole tablet (125 mg, 250 mg, or 500 mg) for the oral suspension.