EXJADE (**deferasirox**) tablets, for oral suspension
JADENU (**deferasirox**) tablets, for oral use
JADENU SPRINKLE (**deferasirox**) granules, for oral use

Preferred product: generic deferasirox

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

The patient must have **ONE** of the following:

1. Chronic iron overload due to blood transfusions
    a. 2 years of age and older
    b. Serum ferritin >1000 mcg/L

2. Non-transfusion-dependent thalassemia (NTDT)
    a. 10 years of age and older
    b. Liver iron concentration (LIC) of at least 5 milligrams of iron per gram of dry liver tissue weight
    c. Serum ferritin >300 mcg/L

AND ALL of the following:

1. Platelet counts >50,000 per microliters
2. Obtain baseline transaminases (AST and ALT) and bilirubin before initiation of therapy and every 2 weeks during the first month and at least monthly thereafter
3. **Brand Exjade ONLY:** Patient **MUST** have tried the preferred product (generic Exjade: deferasirox) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)
4. **Brand Jadenu ONLY:** Patient **MUST** have tried the preferred product (generic Jadenu: deferasirox) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. High-risk myelodysplastic syndromes (MDS)

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2. Advanced malignancies
3. Severe (Child-Pugh C) hepatic impairment
4. Serum creatinine greater than 2 times the age-appropriate upper limit of normal
5. Creatinine clearance less than 40 mL/min
6. Concurrent therapy with another iron chelating agent (see Appendix 1)

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Diagnoses

The patient must have **ONE** of the following:

1. Chronic iron overload due to blood transfusions
   a. 2 years of age and older
   b. Serum ferritin >500 mcg/L
2. Non-transfusion-dependent thalassemia (NTDT)
   a. 10 years of age and older
   b. Liver iron concentration (LIC) of at least 5 milligrams of iron per gram of dry liver tissue weight
   c. Serum ferritin >300 mcg/L

AND ALL of the following:

1. Platelet count >50,000 per microliters
2. Transaminases (AST and ALT) and bilirubin monitored monthly
3. **Brand Exjade ONLY:** Patient **MUST** have tried the preferred product (generic Exjade: deferasirox) unless the patient has a valid medical exception (e.g. inadequate treatment response, intolerance, contraindication)
4. **Brand Jadenu ONLY:** Patient **MUST** have tried the preferred product (generic Jadenu: deferasirox) unless the patient has a valid medical

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exception (e.g. inadequate treatment response, intolerance, contraindication)

AND NONE of the following:

1. High-risk myelodysplastic syndromes (MDS)
2. Advanced malignancies
3. Severe (Child-Pugh C) hepatic impairment
4. Serum creatinine greater than 2 times the age-appropriate upper limit of normal
5. Creatinine clearance less than 40 mL/min
6. Concurrent therapy with another iron chelating agent (see Appendix 1)

Prior - Approval *Renewal* Limits

Same as above

Appendix 1 - List of Iron Chelating Agents

Generic Name	Brand Name
deferiprone	Ferriprox
deferasirox	Exjade
deferasirox	Jadenu