UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Iron Chelators

Program	Prior Authorization
Medication	Exjade (deferasirox), Jadenu (deferasirox) tablet, Jadenu (deferasirox) sprinkle, Ferriprox (deferiprone) tablet and oral solution
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	3/2018
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Exjade® (deferasirox) and Jadenu® (deferasirox) are iron chelating agents indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. The safety and efficacy of Exjade and Jadenu, when administered with other iron chelation therapy, have not been established. It is recommended that therapy with Exjade or Jadenu be started when a patient has evidence of chronic transfusional 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. Exjade and Jadenu are also indicated for the 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 (Fe/g 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. An improvement in survival or disease-related symptoms has not been established.[1, 3]

For patients who are currently on chelation therapy with Exjade tablets for oral suspension and converting to Jadenu tablets, the dose of Jadenu should be approximately 30% lower, rounded to the nearest whole tablet.

Ferriprox® (deferiprone) is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival. Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.[2]

Exjade and Jadenu (deferasirox) contain a black box warning for renal failure, hepatic failure, and gastrointestinal hemorrhage. Ferriprox (deferiprone) contains a black box warning for agranulocytosis/neutropenia.

2. Coverage Criteria:

A. Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)

1. Exjade and Jadenu

a. **Initial Authorization**

(1) **Exjade** or **Jadenu** will be approved based on the following criterion:

(a) Diagnosis of chronic iron overload (e.g., sickle cell anemia, thalassemia, etc.) due to blood transfusion

Authorization will be issued for 12 months

b. **Reauthorization**

(1) **Exjade** or **Jadenu** will be approved based on the following criterion:

(a) Documentation of positive clinical response to Exjade or Jadenu therapy

Authorization will be issued for 12 months

2. Ferriprox

a. **Initial Authorization**

(1) **Ferriprox** will be approved based on **both** of the following criteria:

(a) Diagnosis of transfusional iron overload due to thalassemia syndromes

-AND-

(b) Current chelation therapy is inadequate [e.g., Desferal (deferoxamine), Exjade (deferasirox)]

Authorization will be issued for 12 months

b. **Reauthorization**

(1) **Ferriprox** will be approved based on the following criterion:

(a) Documentation of positive clinical response to Ferriprox therapy

Authorization will be issued for 12 months

B. Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes

1. Initial Authorization

a. **Exjade** or **Jadenu** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic iron overload in non-transfusion dependent thalassemia syndrome

-AND-

(2) Patient has liver iron (Fe) concentration (LIC) levels consistently ≥ 5 mg Fe per gram of dry weight prior to initiation of treatment with Exjade or Jadenu

-AND-

(3) Patient has serum ferritin levels consistently > 300 mcg/L prior to initiation of treatment with Exjade or Jadenu

Authorization will be issued for 12 months

2. Reauthorization

a. **Exjade** or **Jadenu** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Exjade or Jadenu therapy

Authorization will be issued for 12 months

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-

10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

- Supply limits may be in place.

4. References:

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.
2. Ferriprox [package insert]. Rockville, MD: ApoPharma USA, Inc.; February 2020.
3. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

Program	Prior Authorization
Change Control	
Date	Change
3/2018	Archived Deferasirox Products policy and adopted Employer and Individual's Iron Chelator policy.
9/2018	Minor update to the background. Updated references.
9/2019	Annual review. Updated background and references.
9/2020	Annual review. No changes to coverage criteria. Updated references. Added Additional Clinical Rules section.