UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1050-11
Program	Prior Authorization/Notification – Iron Chelators
Medication	Exjade® (deferasirox), Jadenu® (deferasirox), and Ferriprox® (deferiprone)
P&T Approval Date	1/2012, 2/2013, 7/2013, 5/2014, 5/2015, 10/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 6/2021
Effective Date	9/1/2021; Oxford only: 9/1/2021

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 (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (mg 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.

Ferriprox® (deferiprone) is an iron chelator indicated for the treatment of transfusional iron overload in adult and pediatric patients with thalassemia syndromes, sickle cell disease or other anemias. Ferriprox Tablets are indicated in patients ≥ 8 years of age and Ferriprox Oral Solution is indicated in patients ≥ 3 years of age. Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with myelodysplastic syndrome or in patients with Diamond Blackfan anemia.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria:

A. <u>Chronic Iron Overload Due to Blood Transfusions (i.e., Transfusional Iron Overload)</u>

1. <u>Exjade and Jadenu</u>

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. <u>Ferriprox</u>

a. **Initial Authorization**

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

(a) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease or other anemias

-AND-

(b) Ferriprox will not be used for the treatment of transfusional iron overload due to myelodysplastic syndrome or Diamond Blackfan anemia.

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. <u>Chronic Iron Overload in Non-Transfusion Dependent Thalassemia Syndromes</u>

1. <u>Initial Authorization</u>

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

(1) Diagnosis of chronic iron overload in non-transfusion dependent thalassemia (NTDT) 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. <u>Reauthorization</u>

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.
- Step therapy may be in place.

4. References:

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

2. Ferriprox Tablets [package insert]. Toronto, Ontario, Canada: Apotex Inc.; April 2021.
3. Ferriprox Oral Solution [package insert]. Toronto, Ontario, Canada: Apotex Inc.; April 2021.
4. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2020.

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Change Control	
5/2014	Annual review with no change to coverage.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
5/2015	Annual review. Minor formatting with no change to clinical intent. Background and references updated.
10/2015	Added Jadenu (deferasirox) to program for the indications of chronic iron overload due to blood transfusions and non-transfusion dependent Thalassemia Syndromes. Revised criteria for Exjade and Jadenu for chronic iron overload due to blood transfusion. Revised criteria for Ferriprox for transfusional iron overload due to thalassemia syndromes. Background and references updated.
9/2016	Annual review. No changes to coverage criteria. Updated references.
9/2017	Annual review. No changes to coverage criteria. Updated references.
9/2018	Annual review. No changes to coverage criteria. Updated references.
9/2019	Annual review. No changes to coverage criteria. Updated references.
9/2020	Annual review. No changes to coverage criteria. Updated references.
6/2021	Updated coverage criteria for Ferriprox per changes to the FDA approved label. Updated background and references.