Commercial/Healthcare Exchange PA Criteria

Effective: April 27, 2020

Prior Authorization: Iron Chelators – Deferasirox

Products Affected: Jadenu (deferaxirox) oral tablet, Jadenu Sprinkle (deferasirox) granule, Exjade (deferasirox) oral tablet for suspension, deferasirox oral granule, deserasirox oral tablet, deferasirox tablet for suspension

Medication Description

Exjade and Jadenu are oral iron chelators used to bind excess iron in the blood. Exjade and Jadenu are used for the treatment of patients with elevated blood iron levels due to repeated transfusion or for patients with an inherited disorder called non-transfusion-dependent thalassemia (NTDT). Elevated iron levels in the blood can result in the formation of insoluble ferritin which over time can lead to organ damage. Although NTDT usually does not require individuals to get frequent red blood cell transfusions, some patients with NTDT are still at risk for iron overload that can lead to organ damage

Covered Uses:

1. Treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older.
2. 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 concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L.

Exclusion Criteria:

1. Estimated GFR less than 40 mL/min/1.73 m2
2. High-risk myelodysplastic syndromes
3. Advanced Malignancies
4. Platelet counts <50 x 10^9/L
5. Patients with poor performance status
6. Known hypersensitivity to deferasirox

Required Medical Information:

1. Diagnosis
2. Serum ferritin
3. Serum creatinine/creatinine clearance
4. Platelet count
5. Liver iron concentration (LIC) (for NTDT only)

Age Restrictions:

Transfusional Iron Overload: 2 years of age and older
Iron overload in Non-Transfusion-Dependent Thalassemia Syndromes: 10 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 Months

Other Criteria:

Chronic Iron Overload Due to Blood Transfusions

A. Patient has a diagnosis of chronic iron overload due to blood transfusions; **AND**
B. Patient has serum ferritin greater than 1000 mcg/L

Chronic Iron Overload in Non-transfusion-dependent thalassemia (NTDT)

A. Patient has a diagnosis of **chronic iron overload in Non-transfusion-dependent thalassemia (NTDT); AND**
B. Patient has a serum ferritin greater than 300 mcg/L; AND
C. Patient has a liver iron concentration of at least 5 milligrams of iron per gram of dry liver tissue weight.

References:

1. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm336478.htm Accessed March 08, 2016
2. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2015
3. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2015

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	3/8/2016
2	Update	Adopted EH policy Added to new template Removed from CCI PA to indication policy	Reviewed covered uses and exclusion criteria to fda label	4/27/2020

3	Update	Removed Jadenu from Prior Authorization section. Added Jadenu granule, deferasirox granule, deferasirox tablet, deferasirox tablet for suspension, Exjade (deferasirox) oral tablet for suspension, to products affected Updated covered uses to match FDA label wording Added Diagnosis to Required medical information Exclusion criteria: Removed “use in combination with other iron chelation therapy” . Removed “serum creatinine greater than 2 times the age appropriate upper limit of normal or creatinine clearance less than 40mL/min. Added: Estimated GFR less than 40 mL/min/1.73 m2 Reformatted “other criteria” section	Prior authorization Products affected Covered uses Exclusion Criteria Required medical Information Other Criteria	9/4/2020