Jadenu (deferasirox)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Jadenu (deferasirox)

APPROVAL CRITERIA

Requests for Jadenu (deferasirox) may be approved for the following criteria:

I. Treatment of chronic iron overload due to blood transfusions **AND**
   A. Individual is 2 years of age or older;

OR

II. Treatment of chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndrome; **AND**
   A. Individual is 10 years of age or older; **AND**
   B. Documentation is provided that liver iron concentration (LIC) is at least 5 mg Fe/gm of dry weight; **AND**
   C. Documentation is provided that serum ferritin is greater than (>) 300 mcg/L;

OR

III. Treatment of iron overload in individuals diagnosed with myelodysplastic syndromes (MDS) who are at lower risk or potential transplant (NCCN 2A); **AND**
   A. Individual has received or anticipated to receive greater than 20 red blood cell transfusions; **OR**
   B. Documentation is provided that individual initially presents with serum ferritin levels greater than 2500 ng/mL.

Requests for **brand** Jadenu must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Documentation is provided that individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic deferasirox agent; **AND**
   A. Generic deferasirox had inadequate response; **OR**
   B. Generic deferasirox caused adverse outcome; **OR**
   C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Requests for Jadenu (deferasirox) may not be approved for any of the following:

I. Individual has renal insufficiency, as defined by creatinine clearance less than (<) 40 mL/min; **OR**
II. Individual has severe (Child Pugh class C) hepatic impairment; **OR**
III. Individual has platelet counts less than 50 x 10^9/L; **OR**
IV. Individual has high-risk MDS.

Note:
Jadenu (deferasirox) has black box warnings for renal toxicity/failure, hepatic toxicity/failure, and gastrointestinal hemorrhage. The use of deferasirox is contraindicated in adults and pediatric individuals with a CrCl < 40 mL/min, those with poor performance status, high-risk MDS, advanced malignancies, and platelet counts less than 50 x 10^9/L. Deferasirox should be avoided in individuals with severe (Child Pugh class C) hepatic impairment and dose adjusted in individuals with moderate (Child Pugh class B) hepatic impairment. Therapy requires close monitoring, including renal and hepatic function tests.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 12, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2023. Updated September 12, 2022. Available from: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed: October 12, 2022.