

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## 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. Liver iron concentration (LIC) is at least 5 mg Fe/gm of dry weight; **AND**
  - C. Serum ferritin 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 candidates who have received greater than (>) 20 red blood cell transfusions (NCCN 2A); **AND**
  - A. Individual has received or anticipated to receive greater than 20 red blood cell transfusions; **OR**
  - B. Individual initially presents with serum ferritin levels greater than 2500 ng/mL.

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  $50 \times 10^9/L$ ; **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

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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individuals with a CrCl < 40 mL/min. 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.: 2019. 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: September 6, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes. Version 1.2020. Updated August 27, 2019. Available from: [https://www.nccn.org/professionals/physician\\_gls/pdf/mds.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf). Accessed: September 6, 2019.