

Generic Name: N/A

Therapeutic Class or Brand Name: Iron Chelating Agents

Applicable Drugs (if Therapeutic Class): Exjade (deferasirox), Jadenu (deferasirox), Ferriprox (deferiprone)

GPI Code: 9310002500, 9310002800

Preferred: Deferasirox tablets (generic), Deferasirox granules (generic), Deferasirox tablets for oral suspension (generic)

Non-preferred: Deferiprone (generic), Exjade, Jadenu, Jadenu sprinkles, Ferriprox, Ferriprox Twice-A-Day

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 9/30/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

- I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:
 - A. Chronic iron overload due to blood transfusions and criteria 1 through 2 are met:
 1. Prescription is for deferasirox OR there must be documentation of clinically significant treatment failure, intolerance, or contraindication to deferasirox and the prescription is for deferiprone.
 2. Documentation that serum ferritin levels are consistently greater than 1,000 mcg/L.
 3. Minimum age requirement:
 - a) Exjade, Jadenu, and generic deferasirox: 2 years old.
 - b) Ferriprox: 18 years old.
 - B. Chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes and criteria 1 through 4 are met:
 1. Prescription is for Exjade, Jadenu, or generic deferasirox.
 2. Documentation that liver iron (Fe) concentration (LIC) level is at least 5 mg Fe per gram of dry weight.
 3. Documentation that serum ferritin levels are consistently greater than 300 mcg/L.
 4. Minimum age requirement: 10 years old.
- II. The prescriber is a Hematologist or Oncologist.
- III. Non-preferred products require a documented clinical reason containing details as to why generic deferasirox is not appropriate or is contraindicated.

EXCLUSION CRITERIA

- Serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance less than 40 mL/min.
- Patients with poor performance status.
- Patients with high-risk myelodysplastic syndromes (MDS).
- Patients with advanced malignancies.
- Patients with platelet counts $<50 \times 10^9/L$.
- Coadministration with other iron chelation therapies.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- The quantity is limited to a maximum of a 30 day supply per fill.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity showing improvement on medication (must include documentation of decreased serum ferritin levels compared with the baseline level), AND documentation that serum ferritin levels have remained consistently greater than the following:
 - 500mcg/L for a diagnosis of Chronic iron overload due to blood transfusions.
 - 300mcg/L for a diagnosis of Chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes.

APPENDIX

N/A

REFERENCES

1. Thalassaemia International Federation. Thalassaemia International Federation (TIF): Guidelines for the management of non-transfusion dependent thalassaemias (NTDT), 2nd edition. Available at: <https://thalassaemia.org.cy/download/guidelines-for-the-management-of-non-transfusion-dependent-thalassaemias-2nd-edition>.
2. Remacha, A., et. al., Guidelines on haemovigilance of post-transfusional iron overload. Blood Transfus. 2013 Jan; 11(1): 128–139. doi: 10.2450/2012.0114-11.
3. Medi-Span®.

4. Exjade® [Package Insert]. East Hanover, NJ: Novartis; July 2020. Available at: <https://www.novartis.us/sites/www.novartis.us/files/exjade.pdf>.
5. Jadenu® [Package Insert]. East Hanover, NJ: Novartis; July 2020. Available at: <https://www.novartis.us/sites/www.novartis.us/files/jadenu.pdf>.
6. Ferriprox® [Package Insert]. Cary, NC: Chiesi USA; April 2020. Available at: https://resources.chiesiusa.com/Ferriprox/FERRIPROX_500MG_PI_US.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.