

SPECIALTY GUIDELINE MANAGEMENT

EXJADE (deferasirox; tablets for suspension) JADENU (deferasirox; tablets)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Chronic iron overload due to blood transfusions (transfusional iron overload)
2. Chronic iron overload in patients with non-transfusion-dependent thalassemia (NTDT) syndromes

All other indications are considered experimental/investigational and are not a covered benefit.

II. INITIAL CRITERIA FOR APPROVAL

A. Chronic Iron Overload due to Blood Transfusions (transfusional iron overload)

Indefinite authorization may be granted for the treatment of chronic iron overload due to blood transfusions when a pretreatment serum ferritin level is greater than 1000 mcg/L.

B. Chronic Iron Overload in Patients with Non-transfusion Dependent Thalassemia Syndromes

Authorization of 12 months may be granted for the treatment of chronic iron overload in members with non-transfusion dependent thalassemia syndromes.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

IV. REFERENCES

1. Exjade [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
2. Jadenu [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2016.
3. Micromedex Solutions [database online]. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: www.micromedexsolutions.com. Accessed November 18, 2016.
4. AHFS DI (Adult and Pediatric) [database online]. Lexi-Comp, Inc. Hudson, OH. Available at: http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed November 18, 2016.
5. Clinical Pharmacology [Internet]. Elsevier. Tampa (FL). Available from: <http://www.clinicalpharmacology.com>. Accessed November 18, 2016.
6. Cappellini MD, Cohen A, Porter J, et al. Guidelines for the management of transfusion dependent thalassaemia (TDT) 3rd Edition [Internet]. *Thalassaemia International Federation* 2014;20:1-253.
7. Hoffbrand AV, Taher A, Cappellini MD. How I treat transfusional iron overload. *Blood* 2012;120(18):3657-69.
8. Taher A, Vichinsky E, Musallam K, et al. Guidelines for the management of non-transfusion dependent thalassaemia (NTDT). *Thalassaemia International Federation* 2013;19:1-120.