 <p>JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE</p>	Johns Hopkins HealthCare LLC Pharmacy Public Pharmacy Management Drug Policies	<i>Policy Number</i>	MEDS005
		<i>Effective Date</i>	01/01/2006
		<i>Review Date</i>	10/16/2019
	<i>Subject</i> Exjade, Jadenu	<i>Revision Date</i>	10/28/2020
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Exjade, Jadenu

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I. POLICY


- A. Exjade and its generic, as well as Jadenu will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
 2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

- A. **Deferasirox** (generic Exjade) may be approved for patients meeting the following criteria:
1. Documentation of one of the following:
 - a. Patient is ten years of age or older and has chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L.
 - b. Patients is two years of age and older and has chronic iron overload due to blood transfusions.
- B. **Jadenu** may be approved for patients meeting the following criteria:
1. Documentation of one of the following:
 - a. Patient is ten years of age or older and has chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron (Fe) concentration (LIC) of at least 5 mg Fe per gram of dry weight (Fe/g dw) and a serum ferritin greater than 300 mcg/L.
 - b. Patients is two years of age and older and has chronic iron overload due to blood transfusions.
 2. Documented trial and inadequate response, or intolerance, with generic deferasirox

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be restricted to 6 months of therapy.
- B. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation showing beneficial patient response.

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IV. EXCLUSIONS

- A. Generic Exjade, or Jadenu will not be approved for the following:
1. Hereditary hemochromatosis
 2. Use in children younger than 2 years of age
 3. Patients with high-risk myelodysplastic syndromes (MDS)
 4. Patients with advanced malignancies
 5. Patients with platelet counts <50 x 10⁹/L
 6. Serum creatinine greater than 2 times the age-appropriate upper limit of normal (ULN) or creatinine clearance (CICr) < 40 mL/min
 7. Concurrent use with another deferasirox product or other iron chelation therapy
 8. Any other indications that are not FDA-approved or guideline-supported
- B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Johns Hopkins HealthCare Pharmacy Policy PHARM20, Step Therapy, Prior Authorization and Quantity Limits
2. Exjade [Product Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporations; 2019 July
3. Jadenu [Product Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporations; 2019 July.

VI. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/15/2015	Addition of Jadenu
07/27/2017	Updated Exclusion section regarding physician samples.
07/01/2018	Removed EHP Line of Business.
09/16/2019	Clarified criteria for Jadenu in relation with generic deferasirox availability
10/28/2020	Clarified authorization durations

Review/Revision Dates: 07/15/2015, 07/27/2017, 09/16/2019, 10/16/2019, 10/28/2020