

Generic Name: Defasirox

Therapeutic Class or Brand Name: Exjade

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 9310002500

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/4/2018

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through II 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. Documentation that serum ferritin levels are consistently greater than 1,000 mcg/L.
 2. Minimum age requirement: 2 years old.
 - B. Chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes and criteria 1 through 3 are met:
 1. Documentation that liver iron (Fe) concentration (LIC) level is at least 5 mg Fe per gram of dry weight.
 2. Documentation that serum ferritin levels are consistently greater than 300 mcg/L.
 3. Minimum age requirement: 10 years old.
- II. The prescriber is a Hematologist or Oncologist.

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 $<50 \times 10^9/L$.

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. https://www.ibx.com/pdfs/providers/pharmacy_information/pharmacy_policies/Chelation_Agents.pdf.
2. <http://www.bmchp.org/~/.media/dd6cce2d0bbf4506886cbf6e1095f9c3.pdf>.
3. <https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fpolicies%2Fcomm-medical-drug%2Fchelation-therapy-non-overload-conditions.pdf>.
4. http://www.fdhc.state.fl.us/medicaid/prescribed_drug/drug_criteria_pdf/Exjade_Criteria.pdf.
5. Medi-Span®.
6. <http://www.pharma.us.novartis.com/product/pi/pdf/exjade.pdf>.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
12/5/2018	1. Removed "http://www.ibx.com/pdfs/providers/pharmacy_information/pharmacy_policies/deferasirox_exjade.pdf." Removed "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Exjade.pdf" Added "https://www.ibx.com/pdfs/providers/pharmacy_information/pharmacy_policies/Chelation_Agents.pdf." Added "https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs

	<p>%2Fpublic%2Fpolicies%2Fcomm-medical-drug%2Fchelation-therapy-non-overload-conditions.pdf" under References.</p>
1/4/2018	<p>1. Policy reviewed: no changes made.</p>
10/9/2016	<p>1. Updated "http://www.bmchp.org/~media/a30c6fd420d943188c429fbdffedc758.pdf" to "http://www.bmchp.org/~media/dd6cce2d0bbf4506886cbf6e1095f9c3.pdf" and "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Exjade.pdf" to "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Exjade.pdf" under References.</p> <p>2. Removed "https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/exjade_hnmc.html" from References (link no longer valid).</p>
8/13/2015	<p>1. Changed "Patients with platelet counts <50 x 10⁹/L" to "Patients with platelet counts <50 x 10⁹/L" under Exclusion Criteria.</p> <p>2. Updated "https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/exjade_natl.html" to "https://www.healthnet.com/static/general/unprotected/html/national/pa_guidelines/exjade_hnmc.html", "http://www.bmchp.org/app_assets/exjade_20120101t145314_en.pdf" to "http://www.bmchp.org/~media/a30c6fd420d943188c429fbdffedc758.pdf", "https://www.oxhp.com/secure/policy/deferasirox_exjade_and_deferiprone_ferriprox.pdf" to "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Exjade.pdf", "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/drug_criteria_pdf/Exjade_Criteria.pdf" to "http://www.fdhc.state.fl.us/medicaid/prescribed_drug/drug_criteria_pdf/Exjade_Criteria.pdf" and "http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/exjade.pdf" to "http://www.pharma.us.novartis.com/product/pi/pdf/exjade.pdf" under References.</p>
2/14/2014	<p>1. Adapted policy to new format.</p> <p>2. Added GPI code.</p> <p>3. Changed criterion I under Prior Authorization Criteria from: "Documentation of a diagnosis of chronic iron overload due to blood transfusions; Documentation that serum ferritin levels are consistently greater than 1,000 mcg/L (as demonstrated with at least two lab values within two months prior to treatment); Documentation that Creatinine Clearance is at least 40 mL/min; Minimum age requirement: 2 years old"</p> <p>to:</p> <p>"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. Documentation that serum ferritin levels are consistently greater than 1,000 mcg/L; 2. Minimum age requirement: 2 years old; B. Chronic iron overload with non-transfusion-dependent thalassemia (NTDT) syndromes and</p>

	<p>criteria 1 through 3 are met: 1. Documentation that liver iron (Fe) concentration (LIC) level is at least 5 mg Fe per gram of dry weight; 2. Documentation that serum ferritin levels are consistently greater than 300 mcg/L; 3. Minimum age requirement: 10 years old".</p> <p>4. Added "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 x 10⁹/L" to Exclusion Criteria.</p> <p>5. Added "The quantity is limited to a maximum of a 30 day supply per fill" under Quantity/Days Supply Restrictions.</p> <p>6. Changed Authorization under Approval Length from "3 months" to "6 months".</p> <p>7. Changed Re-Authorization under Approval Length from "...documentation that serum ferritin levels have remained consistently greater than 500mcg/L (demonstrated by at least 2 lab values in the previous 3 months)" to "...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".</p> <p>8. Updated references to include Medi-Span and oxhp and fdhc policies.</p>
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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.