

<b>Clinical Policy Title:</b>	deferasirox
<b>Policy Number:</b>	RxA.177
<b>Drug(s) Applied:</b>	deferasirox
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Chronic Iron Overload due to Blood Transfusions (must meet all):

1. Diagnosis of chronic iron overload due to blood transfusions;
2. Transfusion history of  $\geq 100$  mL/kg of packed red blood cells [e.g.,  $\geq 20$  units for a 40 kg individual] and a serum ferritin level  $> 1,000$  mcg/L;
3. Member does not have any of the following contraindications (a, b, or c):
  - a. Glomerular filtration rate (GFR)  $< 40$  mL/min/1.73 m<sup>2</sup>;
  - b. Platelet count  $< 50 \times 10^9$ /L;
  - c. Severe (Child-Pugh C) hepatic impairment;
4. Therapy does not include concurrent use of other iron chelators.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

#### B. Chronic Iron Overload due to Non-Transfusion Dependent Thalassemia (NTDT) Syndromes (must meet all):

1. Diagnosis of chronic iron overload due to NTDT;
2. Documentation of serum ferritin level  $> 300$  mcg/L and a LIC  $\geq 5$  mg Fe per gram of dry weight;
3. Therapy does not include concurrent use of other iron chelators;
4. Member does not have any of the following contraindications (a, b, or c):
  - a. Glomerular filtration rate (GFR)  $< 40$  mL/min/1.73 m<sup>2</sup>;
  - b. Platelet count  $< 50 \times 10^9$ /L;
  - c. Severe (Child-Pugh C) hepatic impairment.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Musallam KM, Angastiniotis M, Eleftheriou A, Porter JB. Crosstalk between available guidelines for the management of patients with beta-thalassemia major. Acta Haematol. 2013; 130(2): 64-73. Available at: <https://pubmed.ncbi.nlm.nih.gov/23485589/>. Accessed August 28, 2024.
2. Hoffbrand AV, Taher A, Cappellini MD. How I treat tranfusional iron overload. Blood. November 1, 2012; 120(18): 3657-3669. Available at: <https://pubmed.ncbi.nlm.nih.gov/22919029/>. Accessed August 28, 2024.
3. Taher AT, Viprakasit V, Musallam KM, Cappellini MD. Treating iron overload in patients with non-transfusion-dependent thalassemia. Am J Hematol. 2013; 88(5): 409-415. Available at: <https://pubmed.ncbi.nlm.nih.gov/23475638/>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated;</li> <li>2. Clinical policy was updated: removed preference for Jadenu®, updated verbiage to “Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy”, updated approval duration verbiage;</li> <li>3. References were reviewed and updated.</li> </ol>	07/04/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance..”</li> <li>2. References were reviewed and updated</li> </ol>	02/26/2021	06/10/2021
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3 and I.B.3 were updated to include , “Prescribed by or in consultation with a hematologist “.</li> <li>2. Initial Approval Criteria, I.A.5 and I.B.5 : Updated to include contraindication/adverse event criteria , Member does not have any of the following contraindications:               <ol style="list-style-type: none"> <li>a. Glomerular filtration rate (GFR) &lt; 40 mL/min/1.73 m<sup>2</sup>;</li> <li>b. Platelet count &lt; 50 x 10<sup>9</sup>/L;</li> <li>c. Severe (Child-Pugh C) hepatic impairment;</li> </ol> </li> <li>3. Continued Therapy Approval Criteria II.A.1, and II.B.2 were rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>4. References were reviewed and updated.</li> </ol>	01/05/2022	04/18/2022
Policy was created:	01/18/2023	04/13/2023

1. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Removed “Exjade” from the PA policy.</li> <li>2. Added generic deferasirox to Drug(s) Applied.</li> <li>3. Removed prescriber restrictions.</li> <li>4. Removed age restrictions.</li> <li>5. Removed dose restrictions.</li> <li>6. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>7. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”.</li> <li>8. Removed other reauthorization requirements including positive response to therapy.</li> <li>9. Updated approval duration verbiage.</li> <li>10. References were reviewed and updated.</li> </ol>	08/28/2024	9/13/2024
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Removed Jadenu® from drug applied section.</li> </ol>	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025