Clinical Policy Title:	deferasirox
Policy Number:	RxA.177
Drug(s) Applied:	deferasirox, Jadenu®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	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 ≥ 100 mL/kg of packed red blood cells [e.g., ≥ 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^2;
   b. Platelet count < 50 x 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 ≥ 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^2;
   b. Platelet count < 50 x 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

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: 1. Policy title table was updated; 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; 3. References were reviewed and updated.	07/04/2020	09/14/2020
Policy was reviewed: 1. Continued therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance.." 2. References were reviewed and updated	02/26/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.3 and I.B.3 were updated to include , "Prescribed by or in consultation with a hematologist ". 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: a. Glomerular filtration rate (GFR) < 40 mL/min/1.73 m^2; b. Platelet count < 50 x 10^9/L; c. Severe (Child-Pugh C) hepatic impairment; 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...". 4. References were reviewed and updated.	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: 1. Removed “Exjade” from the PA policy. 2. Added generic deferasirox to Drug(s) Applied. 3. Removed prescriber restrictions. 4. Removed age restrictions. 5. Removed dose restrictions. 6. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 7. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”. 8. Removed other reauthorization requirements including positive response to therapy. 9. Updated approval duration verbiage. 10. References were reviewed and updated.	08/28/2024	9/13/2024