RxAdvance

Clinical Policy Title:	voxelotor
Policy Number:	RxA.624
Drug(s) Applied:	Oxbryta®
Original Policy Date:	05/21/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Sickle Cell Disease (SCD) (must meet all):

1. Diagnosis of SCD with one of the following genotypes (a, b, c or d);
   a. Homozygous hemoglobin S;
   b. Hemoglobin $S\beta^0$ -thalassemia;
   c. Hemoglobin $S\beta^+$-thalassemia;
   d. Hemoglobin SC;
2. Member's baseline Hb level is between ≥ 5.5 to ≤ 10.5 g/dL;
3. Member meets one of the following (a, b, or c):
   a. Oxbryta® is prescribed concurrently with hydroxyurea therapy;
   b. Member has tried and failed therapy with hydroxyurea at up to maximally indicated doses, unless contraindicated or had experienced clinically significant adverse effects;
   c. Member is not a candidate for hydroxyurea therapy;
4. Member meets one of the following (a or b):
   a. Member has experienced at least 1 vaso-occlusive crisis (VOC) within the past 6 months while on hydroxyurea at up to maximally indicated doses;
   b. Member has intolerance or contraindication to hydroxyurea and has experienced at least 1 VOC within the past 12 months;
5. For age ≥ 5 years: Trial and failure of L-glutamine at up to maximally tolerated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. For age ≥ 16 years: Trial and failure of at least 6 months of Adakveo®, unless contraindicated or clinically significant adverse effects are experienced;
7. Trial and failure of blood transfusion(s), unless contraindicated or clinically significant adverse effects are experienced (e.g., cutaneous ulcers, iron overload).

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Sickle Cell Disease (SCD) (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. Yawn BP, Buchanan GR, Afenyi-annan AN, et al. Management of sickle cell disease: summary of the 2014 evidence-based report by expert panel members. JAMA. 2014;312(10):1033-48. Available at: https://pubmed.ncbi.nlm.nih.gov/25203083/. Accessed August 28, 2024.
2. Sickle cell disease - treatment | NHLBI, NIH. Available at: https://www.nhlbi.nih.gov/health/sickle-cell-disease/treatment. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/07/2020	05/21/2020
Policy was reviewed: 1) Continuation therapy criteria II.A.1. rephrased to "Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy 2) References were updated 3) Added additional initial approval criteria – 3, 4, 7; Updated criteria 2, 6. 4) Added additional continued therapy criteria – 3, 4; Updated criteria #2.	01/22/2020	03/09/2021
Policy was reviewed: 1. References were reviewed and updated.	12/01/2021	01/17/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated age criteria from Member age is ≥ 12 years to Member age is ≥ 4 years. 2. References were reviewed and updated.	02/18/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from The member has a diagnosis of sickle cell disease (homozygous hemoglobin S, sickle hemoglobin C disease, hemoglobin Sβ-thalassemia, or other genotypic variants of sickle cell disease) to Diagnosis of SCD with one of the following genotypes (a, b, c or d); a. Homozygous hemoglobin S; b. Hemoglobin Sβ0 thalassemia; c. Hemoglobin Sβ+ thalassemia; d. Hemoglobin SC. 2. Initial Approval Criteria, I.A.8: Updated to include new trial and failure criteria For age ≥ 5 years: Trial and failure of L-glutamine at up to maximally tolerated doses, unless	01/25/2023	04/13/2023

contraindicated or clinically significant adverse effects are experienced. 3. Initial Approval Criteria, I.A.9: Updated to include new trial and failure criteria For age ≥ 16 years: Trial and failure of a 6-month trial of Adakveo®, unless contraindicated or clinically significant adverse effects are experienced. 4. Initial Approval Criteria, I.A.10: Updated to include new trial and failure criteria Trial and failure of blood transfusion(s), unless contraindicated or clinically significant adverse effects are experienced (e.g., cutaneous ulcers, iron overload). 5. References were reviewed and updated.		
Policy was reviewed: 1. Removed prior age criteria. 2. Updated to remove prior pregnancy criteria or attempting pregnancy with immunosuppressive condition. 3. Updated to remove concurrently therapy criteria with Oxbryta. 4. Removed prior dosing criteria. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated to remove concurrently therapy not using Adakveo with Oxbryta. 7. Updated to remove concurrently therapy with hydroxyurea from continued therapy approval. 8. Updated approval duration. 9. References were reviewed and updated.	12/20/2023	01/01/2024
Policy was reviewed: 1. Removed prescriber restrictions. 2. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 3. References were reviewed and updated.	8/28/2024	9/13/2024