RxAdvance

Clinical Policy Title:	hydroxyurea
Policy Number:	RxA.281
Drug(s) Applied:	Siklos®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Sickle Cell Disease (must meet all):

1. Diagnosis of sickle cell disease;
2. Documentation supports inability to use generic hydroxyurea (e.g., contraindications to the excipients in generic hydroxyurea).

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. **Sickle Cell Disease** (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. Brandow A, Carroll C, Creary S, et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Advances. 2020;4(12):2656-2701. Available at: https://ashpublications.org/bloodadvances/article/4/12/2656/460974/American-Society-of-Hematology-2020-guidelines-for. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated. 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid	07/02/2020	09/14/2020

approval duration updated. 6. References were updated.		
Policy was reviewed: 1. Initial approval criteria was updated: Off-label indication “Histiocytic neoplasms (Langerhans Cell Histiocytosis)” was added to I.B.1. 2. References were updated.	05/05/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.B: Updated to be removed as Siklos® is not indicated for oncology indications. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. 4. Continued Therapy Criteria II.A.3.b and II.A.3.c: Updated to be removed Oncology indications: new dose does not exceed 80 mg/kg per day based on weight and Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). 4. References were reviewed and updated.	01/25/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	1/3/2023	4/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed dose restrictions. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed reauthorization requirement for positive response to therapy. 5. Updated approval duration verbiage. 6. References were reviewed and updated.	8/28/2024	9/13/2024