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| Clinical Policy Title: | hydroxyurea |
| Policy Number: | RxA.281 |
| Drug(s) Applied: | Siklos® |
| Original Policy Date: | 02/07/2020 |
| Last Review Date: | 12/11/2025 |
| 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: <ol style="list-style-type: none"> 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 |

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.

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| 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 |
| Policy was reviewed. | 12/05/2024 | N/A |
| Policy reviewed | 12/11/2025 | 12/11/2025 |