

Commercial PA Criteria

Effective: January 1, 2020

Prior Authorization: Siklos and Xromi

Products Affected: Siklos (hydroxyurea) oral tablet, Xromi (hydroxyurea) oral solution

Medication Description: Siklos is an antimetabolite, indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.

Covered Uses: Indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in pediatric patients with sickle cell anemia with recurrent moderate to severe painful crises.

Exclusion Criteria:

1. Patients with a previous hypersensitivity to hydroxyurea or any other component of its formulation.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed

Age Restrictions:

1. Siklos: 2 years of age and older
2. Xromi: 6 months of age and older

Prescriber Restrictions: Prescribed by, or in consultation with, a hematologist or provider that specializes in the treatment of sickle cell disease.

Coverage Duration: 12 months

Other Criteria:

1. Patient has a diagnosis of sickle cell anemia, with a history of moderate to severe painful crises; AND
2. Patient has a documented intolerance, contraindication, or treatment failure with, an adequate trial of generic hydroxyurea.

References:

1. Siklos (hydroxyurea) [prescribing information]. Rosemont, PA: Medunik USA Inc; November 2023.
2. Xromi (hydroxyurea) [prescribing information]. Franklin, TN: Rare Disease Therapeutics Inc; December 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/17/19

March 2025



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2	Update	Addition of Xromi (hydroxyurea) oral solution and pertinent criteria	Products affected Prior Authorization Age Restriction	03/19/2025
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