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| Division: Pharmacy Policy | Subject: Prior Authorization Criteria |
| Original Development Date: Original Effective Date: Revision Date: | May 22, 2025 |

Xromi[®] (hydroxyurea oral solution)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 6 months of age; **AND**
- Patient must have a diagnosis of sickle cell disease with recurrent moderate to severe painful crises; **AND**
- Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease; **AND**
- If the patient is ≥ 2 years of age, patient must have adequate trial and failure on Siklos[®] (hydroxyurea) demonstrated by inadequate response, intolerance or contraindication to therapy; **AND**
- If the patient is ≥ 12 years of age, medical records OR the patient’s medical history must indicate a history of difficulty swallowing (dysphagia), or a medical condition that is characterized by difficulty or inability to swallow.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 100 mg/mL oral solution.
- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>