Pharmacy Medical Necessity Guidelines:
Siklos® (hydroxyurea)

Effective: March 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Siklos (hydroxyurea) 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.

COVERAGE GUIDELINES

The plan may authorize coverage of **Siklos (hydroxyurea)** for Members when the following criteria are met:

1. Documented diagnosis of sickle cell anemia

AND

2. The patient is at least two years of age or older

AND

3. Prescribed by or in consultation with a hematologist or sickle cell disease specialist

AND

4. Documentation the patient requires a dispersible tablet due to a clinical condition such as but not limited to:
   a. Dysphagia
   b. Patient age

LIMITATIONS

None

CODES

None

REFERENCES

1. Brawley OW, Cornelius LJ, Edwards LR et al. National institutes of health consensus development conference statement: hydroxyurea treatment for sickle cell disease. Ann Intern Med. 2008;148(12):932
2. Liem RI, Lanzkron S, Coates TD, et al. American Society of Hematology 2019 guidelines for sickle cell disease: cardiopulmonary and kidney disease. Blood Adv. 2019; 3(23):3867-3897.
3. National Institutes of Health, National Heart, Lung, and Blood Institute. (2014). Evidence-based management of sickle cell disease: expert panel report, 2014. Retrieved from https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease.
4. Siklos (hydroxyurea) [package insert]. Rosemont, PA: Medunik USA Inc.; November 2023.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee

- June 13, 2023: No changes
- May 14, 2024: No changes
- March 11, 2025: No changes
- March 10, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for

selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services