

## Pharmacy Medical Necessity Guidelines: Siklos® (hydroxyurea)

Effective: June 9, 2020

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: <b>Commercial Products</b> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans <ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <b>Tufts Health Public Plans Products</b> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan		<b>Fax Numbers:</b>  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. Member is 2 to 18 years of age
- AND**
3. Documentation the Member requires a dispersible tablet due to a clinical condition such as but not limited to:
    - a. Dysphagia
    - b. Member age

### LIMITATIONS

- Siklos (hydroxyurea) will not be covered in Members ≥19 years of age.
- Authorization of Siklos (hydroxyurea) will be provided through 18 years of age.

### CODES

None

### REFERENCES

- Siklos [package insert]. Rosemont, PA: Medunik USA Inc.; May 2019.

### APPROVAL HISTORY

November 13, 2018: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

- September 10, 2019: No changes
- June 9, 2020: 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.