MEDICAL MUTUAL®

Drug Policy

Policy:	**Hydroxyurea Preferred Step Therapy**	**Annual Review Date:** **11/21/2019**
Impacted Drugs:	**Siklos (hydroxyurea) tablets**	**Last Revised Date:** **11/21/2019**

OVERVIEW

Sickle cell disease (SCD), a multisystem disorder, is the most common condition caused by a single gene mutation. SCD is characterized by the presence of abnormal erythrocytes damaged by the sickle hemoglobin (HbS) gene. This variant of the normal adult hemoglobin (HbA) can be inherited from both parents or from one parent along with another variant, such as hemoglobin C (HbC) or with β-thalassemia. SCD can lead to pain crises when sickle cells block blood flow and decrease oxygen delivery; pain episodes can be acute or chronic. Other complications associated with SCD include severe anemia, brain complications (e.g., stroke), heart disease, pulmonary hypertension, kidney and liver complications, joint complications, gallstones, and infections.

Both Droxia and Siklos are indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in patients with SCD with recurrent moderate to severe painful crises. Siklos is indicated for use in patients 2 years of age and older. The safety and effectiveness of Droxia in pediatric patients have not been established but the National Institutes of Health (NIH) – National Heart, Lung, and Blood Institute Evidence-Based Management of SCD, Expert Panel Report (2014) recommends Droxia for use in pediatric and adult patients.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one preferred medication within the 180-day look-back period are excluded from step therapy.

Preferred Medications

- Generic hydroxyurea capsules
- Droxia (hydroxyurea)
- Hydrea (hydroxyurea)

Non-Preferred Medications

- Siklos

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PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

2. Exceptions for Siklos can be made for a patient who requires the Siklos 100 mg strength to achieve a dosage that cannot be achieved with the available strengths of the preferred products.

3. Exceptions for Siklos can be made for a patient who cannot swallow or has difficulty swallowing Droxia, Hydrea, or generic hydroxyurea capsules.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

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Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Hydroxyurea. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 14 August 2019. Accessed on 20 November 2019.
2. Droxia® capsules [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; December 2018.
3. Siklos® tablets [prescribing information]. Bryn Mawr, PA: Medunik USA Inc; August 2018.