Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PMN.193	**Effective Date: 04/2019** **Revision Date: 04/15/2020**
Policy Name: Hydroxyurea (Siklos)	

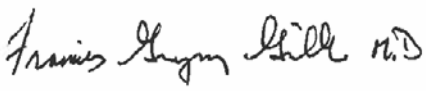
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2020 annual review: references reviewed and updated

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Hydroxyurea (Siklos)

Reference Number: PA.CP.PMN.193
Effective Date: 4.17.19
Last Review Date: 04/2020

Revision Log

Description
Hydroxyurea (Siklos®) is an antimetabolite.

FDA Approved Indication(s)
Siklos is 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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Siklos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Sickle Cell Disease (must meet all)**:**

1. Diagnosis of sickle cell disease;
2. Age ≥ 2 years;
3. Documentation supports inability to use generic hydroxyurea (e.g., contraindications to the excipients in generic hydroxyurea, inability to accommodate prescribed weight-based dose with 500 mg capsule);
4. Dose does not exceed 35 mg/kg per day based on weight.

Approval duration: 12 months

B. Oncology Indications (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d);
   a. Acute myeloid leukemia;
   b. Chronic myeloid leukemia;
   c. Head and neck cancer;
   d. Myeloproliferative neoplasms (myelofibrosis, polycythemia vera, essential thrombocythemia);
2. Age ≥ 2 years;
3. Documentation supports inability to use generic hydroxyurea (e.g., contraindications to the excipients in generic hydroxyurea);
4. Request meets one of the following (a or b):
   a. Dose does not exceed 80 mg/kg per day based on weight;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):
   a. Sickle cell disease: new dose does not exceed 35 mg/kg per day based on weight;
   b. Oncology indications: new dose does not exceed 80 mg/kg per day based on weight;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hydroxyurea (Hydrea®, Droxia®)	Sickle cell disease: 15 mg/kg PO QD CML: 40 mg/kg/day Head and neck cancer: 1,000 mg q12h	Sickle disease: 35 mg/kg/day Oncology indications: 80 mg/kg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): myelosupression and malignancies

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Sickle cell disease	Initial dose 20 mg/kg PO QD. Dose may be increased by 5 mg/kg/day every 8 weeks or sooner if a severe painful crisis occurs.	35 mg/kg/day (maximum dose based on weight)

VI. Product Availability

Tablets: 100 mg, 1,000 mg

VII. References

1. Siklos Prescribing Information. Bryn Mawr, PA: Medunik USA, Inc.; May 2019. Available at https://www.siklosusa.com/. Accessed February 13, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2016. Available at: http://www.clinicalpharmacology-ip.com. Accessed February 13, 2020.
3. Lexicomp Online [Internet Database]. Hudson, Ohio: Wolters Kluwer Clinical Drug Information, Inc. Updated periodically. Accessed February 13, 2020.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 12, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.17.19	
2Q 2020 annual review: references reviewed and updated	04/2020	