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: 02/01/2020**
Policy Number: PA.CP.PHAR.437	**Effective Date: 01/15//2020** **Revision Date: 01/15/2020**
Policy Name: Thioguanine (Tabloid)	

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:

New Policy Created

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

Clinical Policy: Thioguanine (Tabloid)

Reference Number: PA.CP.PHAR.437
Effective Date: 01/2020
Last Review Date: 01/2020 Revision Log

Description
Thioguanine (Tabloid®) is an antimetabolite.

FDA Approved Indication(s)
Tabloid is indicated for

- Remission induction and remission consolidation treatment of acute nonlymphocytic leukemias *[also known as acute myeloid leukemia; AML per the National Cancer Institute's Dictionary of Cancer Terms]*.

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 Tabloid is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Myeloid Leukemia or Acute Lymphoblastic Leukemia (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Acute myeloid leukemia (AML);
   b. Acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Request meets one of the following (a, b, or c):
   a. Dose does not exceed 3 mg/kg per day;*
   b. Dose does not exceed 200 mg/m^2 per day;*
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant labeled or off-label use (*prescriber must submit supporting evidence*).

**Tabloid dosing and duration (usually short-term) is individualized and protocol driven.*

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Acute Myeloid Leukemia or Acute Lymphoblastic Leukemia (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. New dose does not exceed 3 mg/kg per day;*
   b. New dose does not exceed 200 mg/m^2 per day;*
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant labeled or off-label use (*prescriber must submit supporting evidence*).

**Tabloid dosing and duration (usually short-term) is individualized and protocol driven.*

Approval duration: 3 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

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 policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AML: acute myeloid leukemia
ALL: acute lymphoblastic leukemia
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Center

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): thioguanine should be not used in patients whose disease has demonstrated prior resistance to this drug.
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
AML	Induction and consolidation therapy: • ***Single-agent therapy*** *(Package Insert):** 2 mg/kg/day PO; after 4 weeks may increase to 3 mg/kg/day if no clinical improvement or myelosuppression; total daily dosage may be administered at one time; ***adjust accordingly for combination therapy.*** **Thioguanine alone is seldom justified for initial AML remission induction because combination chemotherapy, including thioguanine, results in more frequent remission induction and longer remission duration (PI).* • ***Combination therapy*** *(Clinical Pharmacology):* Usually in combination with cytarabine. 100 mg/m^2 PO every 12 hours for 5 to 10 days • ***Combination therapy*** *(Micromedex):** With other cytotoxic agents. Induction: 100 mg/m^2 PO BID for 8 to 21 days Maintenance: 40 mg/m^2 PO BID on days 1 to 4 weekly, or 100 mg/m^2 PO BID on days 1 to 4 every 3 to 4 weeks **Skeel RT: Handbook of Cancer Chemotherapy, 3rd. Little, Brown and Company, Boston, MA, 1991.* _____ Clinical Pharmacology notes that the dose should be rounded to the nearest 20 mg. The package insert notes that Tabloid is not recommended for use during maintenance therapy or similar long-term continuous treatments due to the high risk of liver toxicity - and that the dosage which will be tolerated and effective varies according to the stage and type of neoplastic process being treated.	Varies
ALL *(off-label)*	Induction and consolidation therapy: • ***Combination therapy*** *(Clinical Pharmacology):* The usual dosage, when used in combination chemotherapy for induction of remission in patients with acute leukemia, ranges from 75 to 200 mg/m^2 PO per day, given in 1 or 2 divided doses for 5 to 7 days of the treatment course, or until remission is attained. Typical maintenance dosage is 2 to 3 mg/kg/day, or 100 mg/m^2/day PO. Induction and consolidation therapy, and relapse/refractory disease: • ***Combination therapy*** *(NCCN Compendium - Pediatric ALL (category 2A):* o Consolidation therapy, as a component of: ▪ EsPhALL regimen (COG AALL1122 or SR arm of COG AALL1631) + imatinib or dasatinib and an HR backbone of the Berlin-Frankfurt-Münster regimen for Ph-positive B-ALL	Varies

Indication	Dosing Regimen	Maximum Dose
	▪ Interfant regimens for infant ALL (post-consolidation, and high risk arm not undergoing transplant (HSCT)) o Therapy for relapsed/refractory Ph-negative B-ALL, or in combination with dasatinib or imatinib for relapsed/refractory Ph-positive B-ALL as a component of ALL-REZ BFM 90 regimen _____ Clinical Pharmacology notes that the dose should be rounded to the nearest 20 mg. The package insert notes that Tabloid is not recommended for use during maintenance therapy or similar long-term continuous treatments due to the high risk of liver toxicity - and that the dosage which will be tolerated and effective varies according to the stage and type of neoplastic process being treated.	

VI. Product Availability

Tablet: 40 mg

VII. References

1. Tabloid Prescribing Information. Mason,OH: Prasco Laboratories; May 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/012429s028lbl.pdf. Accessed August 9, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 22, 2019.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed July 22, 2019.
4. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 22, 2019.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed October 11, 2019.
6. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed October 16, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	01/20	

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