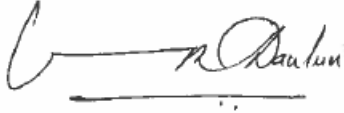


Prior Authorization Review Panel

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: 11/01/2021
Policy Number: PA.CP.PHAR.437	Effective Date: 01/2020 Revision Date: 10/2021
Policy Name: Thioguanine (Tabloid)	
<p>Type of Submission – <u>Check all that apply:</u></p> <p> <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review - No Revisions <input type="checkbox"/> Statewide PDL - <i>Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.</i> </p>	
<p>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</p> <p>Please provide any changes or clarifying information for the policy below:</p> <p>4Q 2021 annual review: moved requirement for use as remission induction/consolidation from ALL to AML per FDA label and NCCN; for ALL, specified that disease should be relapsed/refractory and added requirement for use in combination with imatinib or Sprycel if Ph+ per NCCN; references reviewed and updated.</p>	
<p>Name of Authorized Individual (Please type or print):</p> <p>Venkateswara R. Davuluri, MD</p>	<p>Signature of Authorized Individual:</p> 

Clinical Policy: Thioguanine (Tabloid)

Reference Number: PA.CP.PHAR.437

Effective Date: 01/2020

Last Review Date: 10/2021

[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*]. However, it is not recommended for use during maintenance therapy or similar long-term continuous treatments due to the high risk of liver toxicity.

Tabloid is not effective in chronic lymphocytic leukemia, Hodgkin's lymphoma, multiple myeloma, or solid tumor.

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 (must meet all):

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

Approval duration: 3 months

B. Acute Lymphoblastic Leukemia (off-label) (must meet all):

1. Diagnosis of relapsed/refractory acute lymphoblastic leukemia (ALL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age < 18 years;
4. Disease is one of the following (a or b):
 - a. Philadelphia chromosome-negative;
 - b. Philadelphia chromosome-positive, and prescribed in combination with Sprycel[®] or imatinib;

5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 3 months

C. 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 (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tabloid for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
 - a. New dose does not exceed 3 mg/kg per day;
 - c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant labeled or off-label use (*prescriber must submit supporting evidence*).

Approval duration: 3 months

B. Acute Lymphoblastic Leukemia (off-label) (must meet all):

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tabloid for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration: 3 months

C. 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	<p>Induction and consolidation therapy:</p> <ul style="list-style-type: none"> • Combination therapy: <ul style="list-style-type: none"> ○ Because the usual therapies for adult and pediatric acute nonlymphocytic leukemias involve the use of thioguanine with other agents in combination, physicians responsible for administering these therapies should be experienced in the use of cancer chemotherapy and in the chosen protocol. • Single agent therapy: <ul style="list-style-type: none"> ○ On those occasions when single-agent chemotherapy with thioguanine may be appropriate, the usual initial dosage for pediatric patients and adults is approximately 2 mg/kg of body weight per day. If, after 4 weeks on this dosage, there is no clinical improvement and no leukocyte or platelet depression, the dosage may be cautiously increased to 3 mg/kg/day. The total daily dose may be given at one time. <p>Maintenance therapy:</p> <ul style="list-style-type: none"> • Thioguanine is not recommended for use during maintenance therapy or similar long-term continuous treatments due to the high risk of liver toxicity. 	Varies

VI. Product Availability

Tablet: 40 mg

VII. References

1. Tabloid Prescribing Information. Mason,OH: Prasco Laboratories; May 2018. Available at <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=4490128b-e73f-4849-9d6e-e8591639d771>. Accessed July 15, 2021.

2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 28, 2021.
3. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed July 15, 2021.
4. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed July 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New Policy Created	01/20	
4Q 2020 annual review: AML dosing information limited to package insert information or directive for providers to forward protocol dosing information (there is no NCCN guidance here); the off-label ALL criteria is presented separately with standard off-label dosing language; references reviewed and updated.	08/20	11/20
4Q 2021 annual review: moved requirement for use as remission induction/consolidation from ALL to AML per FDA label and NCCN; for ALL, specified that disease should be relapsed/refractory and added requirement for use in combination with imatinib or Sprycel if Ph+ per NCCN; references reviewed and updated.	10/2021	