

Generic Name: Thioguanine

Preferred: N/A

Therapeutic Class or Brand Name: Tabloid

Non-preferred: N/A

Applicable Drugs: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following diagnoses must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Acute nonlymphocytic leukemia and meets one of the following i or ii:
 - i. Used during remission induction treatment.
 - ii. Used during remission consolidation treatment.
 - Other Uses With Supportive Evidence
 - B. Acute lymphoblastic leukemia (ALL)
- II. Minimum age requirement: 1 year old and older.
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Maintenance therapy or similar long-term continuous treatment
- Chronic lymphocytic leukemia
- Hodgkin's lymphoma
- Multiple myeloma
- Solid tumors

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities are limited to a 30-day supply
- Tablets: 40 mg
- Acute nonlymphocytic leukemia
 - Adult and pediatric initial dose: 2 mg/kg/day
 - Adult and pediatric maximum dose: 3 mg/kg/day
- ALL
 - See appendix for specific dosing

APPROVAL LENGTH

- **Authorization:** 4 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- Acute Lymphoblastic Leukemia (ALL)
 - ESPHAL + TKI Treatment - Reinduction
 - Dose: 60mg/m² orally daily days 36-49 of a 63-day cycle (with dexamethasone, vincristine, doxorubicin, L-asparaginase, cyclophosphamide, methotrexate and TKI)
 - CALGB 10403 Regimen – Delayed Intensification
 - Dose: 60 mg/m² orally daily days 29 to 42 of a 56-day cycle (with vincristine, dexamethasone, doxorubicin, pegaspargase, cyclophosphamide, cytarabine, intrathecal methotrexate)
 - USC/MSKCC ALL Regimen based on CCG-1882 Regimen – Reinduction 1 & 2
 - 60 mg/m² orally daily days 29 to 42 of a 43-day cycle (with daunorubicin, vincristine, pegaspargase, dexamethasone, methotrexate, intrathecal hydrocortisone, cyclophosphamide, and cytarabine)
 - CALGB 8811 Larson Regimen – Course IV Late Intensification
 - 60 mg/m² orally daily on days 29 to 42 of a 56-day cycle (with doxorubicin, vincristine, dexamethasone, cyclophosphamide, and cytarabine)
 - ALL MRC UKALLXII/ECOG E2993 Regimen – Consolidation Cycle 3
 - 60 mg/m² orally daily on days 29 to 42 of a 42-day cycle (with daunorubicin, cyclophosphamide, and cytarabine)

- CALGB 9111 – Course IV: Late Intensification
 - 60 mg/m² orally daily on days 29 to 42 of a 56-day cycle

REFERENCES

1. Tabloid. Prescribing Information. Waylis Therapeutics, LLC. July 2024. Accessed April 11, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2024/012429s029lbl.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Pediatric Acute Lymphoblastic Leukemia. Version 3.2025. Updated March 17, 2025. Accessed April 11, 2025. www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Acute Lymphoblastic Leukemia. Version 3.2024. Updated December 20, 2024. Accessed April 11, 2025. www.nccn.org/professionals/physician_gls/pdf/all.pdf
4. Larson RA, Dodge RK, Linker CA, et al. A randomized controlled trial of filgrastim during remission induction and consolidation chemotherapy for adults with acute lymphoblastic leukemia: CALGB study 9111. *Blood*. 1998;92(5):1556-64. PMID: 9716583.
5. Biondi A, Schrappe M, De Lorenzo P, et al. Imatinib after induction for treatment of children and adolescents with Philadelphia-chromosome-positive acute lymphoblastic leukaemia (EsPhALL): a randomised, open-label, intergroup study. *Lancet Oncol*. 2012 Sep;13(9):936-45. doi:10.1016/S1470-2045(12)70377-7.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.