


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.

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| Plan: PA Health & Wellness | Submission Date: 05/01/2021 |
| Policy Number: PA.CP.PHAR.447 | Effective Date: 01/2020 Revision Date: 04/2021 |
| Policy Name: Mercaptopurine (Purixan) | |
| <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>2Q 2021 annual review: corrected dosing typo; references reviewed and updated.</p> | |
| Name of Authorized Individual (Please type or print): Auren Weinberg, MD | Signature of Authorized Individual:  |

Clinical Policy: Mercaptopurine (Purixan)

Reference Number: PA.CP.PHAR.447

Effective Date: 01/2020

Last Review Date: 04/2021

[Revision Log](#)

Description

Mercaptopurine (Purixan[®]) is a nucleoside metabolic inhibitor that is an analogue of the purine bases adenine and hypoxanthine.

FDA Approved Indication(s)

Purixan is indicated for the treatment of patients with acute lymphoblastic leukemia (ALL) as part of a combination maintenance therapy regimen.

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

I. Initial Approval Criteria

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

1. Diagnosis of ALL or acute promyelocytic leukemia;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. One of the following (a or b):
 - a. Medical justification supports inability to use mercaptopurine tablets (e.g., contraindications to excipients in mercaptopurine tablets);
 - b. Member has a documented swallowing disorder or an inability to swallow tablets or capsules;
4. Request meets one of the following (a or b):
 - a. Dose does not exceed 2.5 mg/kg or 75 mg/m² per day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 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 Lymphoblastic Leukemia or Acute Myeloid 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 or b):
 - a. New dose does not exceed 2.5 mg/kg or 75 mg/m² per day;
 - b. 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 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 policy – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

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 | Dosing Regimen | Dose Limit/Maximum Dose |
|------------------------------|------------------------------------------------------|---------------------------------------------------------------------------------------------|
| mercaptopurine (Purinethol®) | 1.5 to 2.5 mg/kg (50 to 75 mg/m ²) PO QD | Dose should be adjusted to maintain an absolute neutrophil count (ANC) at a desirable level |

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

None reported

Appendix D: General Information

- Typical maintenance therapy regimen consists of daily 6-mercaptopurine, weekly methotrexate, and monthly vincristine/prednisone pulses for 2-3 years.
- Oral mercaptopurine can have highly variable drug and metabolite concentrations as many factors (e.g. thiopurine S-methyl transferase (TPMT) polymorphisms and drug-drug-interactions with other chemotherapeutic agents) can affect bioavailability and impact the ability of maintenance regimens to prevent disease relapse.
- Mercaptopurine dose adjustments may be needed to manage clinically significant adverse effects (e.g. myelosuppression including anemia, neutropenia, lymphopenia and thrombocytopenia). Mercaptopurine oral suspension may be more amendable to dose adjustments in patients who continue to have poor clinical response despite dose adjustments with the tablet form.
- Micromedex lists mercaptopurine as a Class IIb recommendation for both Crohn’s disease and ulcerative colitis.
- NCCN treatment guidelines for ALL state that lymphoblastic lymphoma is indistinguishable from ALL based on morphologic, genetic, and immunophenotypic features. Patients with lymphoblastic lymphoma generally benefit from treatment with ALL-like regimens.

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|------------------------------------------------------|--------------------------------------------|
| ALL | 1.5 to 2.5 mg/kg (50 to 75 mg/m ²) PO QD | 2.5 mg/kg/day or 75 mg/m ² /day |

VI. Product Availability

Oral suspension: 2000 mg/100 mL (20 mg/mL)

VII. References

1. Purixan Prescribing Information. Leicester, UK: Nova Laboratories Ltd; April 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9fd27952-7787-47d9-b6cf-7af2dc38217b> . Accessed February 12, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 12, 2021.
3. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 12, 2021.
4. National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2021. Available at: www.nccn.org. Accessed February 12, 2021.
5. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 2.2021. Available at: www.nccn.org. Accessed February 12, 2021.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---------------------------------------------------------------------------------|---------|-------------------|
| New Policy Created | 01/2020 | |
| 1Q 2021 annual review: no significant changes; references reviewed and updated. | 01/2021 | |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--------------------------------------------------------------------------------|-------------|--------------------------------------|
| 2Q 2021 annual review: corrected dosing typo; references reviewed and updated. | 04/2021 | |