

PURIXAN™ (mercaptopurine oral suspension)**NATL**

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- For the treatment of patients with acute lymphoblastic leukemia (ALL) as a component of a combination maintenance therapy regimen.

II. Health Net Approved Indications and Usage Guidelines:

- Diagnosis of acute lymphoblastic leukemia
AND
- Failure or clinically significant adverse effects to mercaptopurine tablets
AND
- Member has a documented swallowing disorder or an inability to swallow tablets or capsules

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature

IV. 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.
- The use of mercaptopurine for Chron's disease and ulcerative colitis has the following recommendations as an off-label use: American Hospital Formulary Service (AHFS) states mercaptopurine is effective in the management of fistulizing Crohn's disease, and it is effective in treating pediatric patients with intractable Crohn's disease who have been refractory to corticosteroids, sulfasalazine, and/or anti-infectives, usually for several years. Clinical pharmacology lists mercaptopurine as a recommended off-label use for the treatment of Chron's disease and ulcerative colitis. Micromedex lists mercaptopurine as a recommendation Class IIb for both Chron's disease and ulcerative colitis.
- The use of mercaptopurine for Non-Hodgkin's lymphoma – Lymphoblastic lymphoma has a National Comprehensive Cancer Network (NCCN) compendium category rating of 2A.

PURIXAN™ (mercaptopurine oral suspension)**NATL****V. Therapeutic Alternatives:**

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

*Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Purixan™	1.5 to 2.5mg/kg (50 to 75 mg/m ²) PO QD	Length of Benefit

VII. Product Availability:

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

VIII. References:

1. Purixan [Prescribing Information] Leicester, UK: Nova Laboratories Ltd; December 2014.
2. Mercaptopurine. American Hospital Formulary Service Drug Information. Available at: <http://www.medicinescomplete.com/mc/ahfs/current/>. Accessed January 7, 2016.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. January 7, 2016.
4. Clinical Pharmacology Web site. Available at: <http://clinicalpharmacology-ip.com>. Accessed January 7, 2016.
5. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 7, 2016.

National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia Version 1.2015. Available at: http://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed January 7, 2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.