Reference number(s)
2982-A

Specialty Guideline Management
Purixan

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Purixan	mercaptopurine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications

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

Compendial Uses

- ALL / Lymphoblastic lymphoma (LL)
- Acute promyelocytic leukemia (APL)
- Moderate to Severe Crohn's Disease (CD)

All other indications are considered experimental/investigational and not medically necessary.

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Documentation

Submission of the following information is necessary to initiate the prior authorization review: Documentation supporting an intolerable adverse event with the generic alternative mercaptopurine (the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information).

Coverage Criteria

Acute lymphoblastic leukemia (ALL)/ Lymphoblastic lymphoma (LL)

Authorization of 12 months may be granted for treatment of ALL/LL when either of the following criteria is met:

- Member has a documented intolerable adverse event with the generic alternative mercaptopurine and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information, OR
- Member is unable to swallow the tablet formulation.

Acute promyelocytic leukemia (APL)

Authorization of 12 months may be granted for treatment of APL when either of the following criteria is met:

- Member has a documented intolerable adverse event with the generic alternative mercaptopurine and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information, OR
- Member is unable to swallow the tablet formulation

Moderate to Severe Crohn's Disease (CD)

Authorization of 12 months may be granted for treatment of moderate to severe CD when either of the following criteria is met:

- Member has a documented intolerable adverse event with the generic alternative mercaptopurine and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information, OR
- Member is unable to swallow the tablet formulation

Continuation of Therapy

ALL/LL and APL

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for ALL/LL or APL when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Moderate to Severe Crohn's Disease (CD)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active CD and who achieve or maintain remission.

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active CD and who achieve or maintain a positive clinical response as evidenced by low disease or improvement in signs and symptoms of the condition where there is improvement in any of the following from baseline:

- Abdominal pain or tenderness
- Diarrhea
- Body weight
- Abdominal mass
- Hematocrit
- Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
- Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

References

1. Purixan [package insert]. Franklin, TN: Rare Disease Therapeutics, Inc.; April 2020.
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3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed June 17, 2024.
4. IBM Micromedex® DRUGDEX ® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com (Accessed: June 17, 2024).
5. Lichtenstein GR, Loftus Jr EV, Isaacs KI, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2018;113:481-517.

6. Feuerstein J, Ho E, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021; 160:2496-2508.