Reference number(s)
2982-A

SPECIALTY GUIDELINE MANAGEMENT

PURIXAN (mercaptopurine)
mercaptopurine

POLICY

I. 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.

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

B. Compendial Uses
1. ALL / Lymphoblastic lymphoma (LL)
2. Acute promyelocytic leukemia (APL)
3. Moderate to Severe Crohn's Disease (CD)

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

II. 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).

III. CRITERIA FOR INITIAL APPROVAL

A. 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:
1. 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
2. Member is unable to swallow the tablet formulation.

B. Acute promyelocytic leukemia (APL)
Authorization of 12 months may be granted for treatment of APL when either of the following criteria is met:
1. 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

2. Member is unable to swallow the tablet formulation

C. 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:

1. 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
2. Member is unable to swallow the tablet formulation

IV. CONTINUATION OF THERAPY

A. 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.

B. 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 moderate to severe 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:

1. Abdominal pain or tenderness
2. Diarrhea
3. Body weight
4. Abdominal mass
5. Hematocrit
6. Endoscopic appearance of the mucosa
7. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

V. REFERENCES

1. Purixan [package insert]. Franklin, TN: Rare Disease Therapeutics, Inc.; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 26, 2021.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia. Version 2.2021. https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed June 7, 2021.
4. IBM Micromedex® DRUGDEX ® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com (Accessed: June 07, 2021).
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.