

SPECIALTY GUIDELINE MANAGEMENT

ALIQOPA (copanlisib)

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

Aliqopa is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

B. Compendial Uses

1. Gastric MALT lymphoma (extranodal marginal zone lymphoma of the stomach), subsequent therapy for relapsed or refractory disease after 2 prior therapies
2. Non-gastric MALT lymphoma (extranodal marginal zone lymphoma of nongastric sites), subsequent therapy for relapsed or refractory disease after 2 prior therapies
3. Nodal marginal zone lymphoma, subsequent therapy as a single agent for relapsed or refractory disease after 2 prior therapies
4. Splenic marginal zone lymphoma, subsequent therapy as a single agent for relapsed or refractory disease after 2 prior therapies

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Follicular Lymphoma (FL)**

Authorization of 12 months may be granted to members with follicular lymphoma (FL) when the requested medication will be used as subsequent therapy after at least two prior therapies.

B. **Gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of the Stomach) and Non-gastric MALT Lymphoma (Extranodal Marginal Zone Lymphoma of Nongastric Sites)**

Authorization of 12 months may be granted to members with gastric or non-gastric mucosa-associated lymphoid tissue (MALT) lymphoma (extranodal marginal zone lymphoma of the stomach and nongastric sites) when the requested medication will be used as subsequent therapy after at least two prior therapies.

C. **Nodal Marginal Zone Lymphoma**

Authorization of 12 months may be granted to members with nodal marginal zone lymphoma when the requested medication will be used as subsequent therapy after at least two prior therapies as a single agent.

D. **Splenic Marginal Zone Lymphoma**

Authorization of 12 months may be granted to members with splenic marginal zone lymphoma when the requested medication will be used as subsequent therapy after at least two prior therapies as a single agent.

Reference number
2329-A

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Aliqopa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; March 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 2, 2023.