

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.

Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

B. Compendial Uses

1. Follicular lymphoma, second-line or subsequent therapy for relapsed or refractory disease after 2 prior therapies
2. Gastric MALT lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
3. Non-gastric MALT lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
4. Nodal marginal zone lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies
5. Splenic marginal zone lymphoma, subsequent therapy for relapsed or refractory disease after 2 prior therapies

All other indications are considered experimental/investigational and are 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 second-line or subsequent therapy.

B. **Gastric MALT Lymphoma and Non-gastric MALT Lymphoma**

Authorization of 12 months may be granted to members with gastric or non-gastric MALT lymphoma 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.

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.

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 who have not experienced unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Aliqopa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; May 2019.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed July 02, 2019.