Reference number
2331-A

STANDARD MEDICARE PART B 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. 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, 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 as a single agent for relapsed or refractory disease after 2 prior therapies
5. Splenic marginal zone lymphoma, subsequent therapy as a single agent for relapsed or refractory disease after 2 prior therapies

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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 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.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with Aliqopa
2. Aliqopa is being used to treat an indication enumerated in Section II
3. The member is receiving benefit from therapy. Benefit is defined as:
    i. No evidence of unacceptable toxicity while on the current regimen or
    ii. No evidence of disease progression while on the current regimen

IV. REFERENCES

1. Aliqopa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; February 2020.
2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. http://www.nccn.org. Accessed July 02, 2019.