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.

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 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 (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.

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:
A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen and
   2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Aliqopa.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: B-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Aliqopa are covered in addition to the following:
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

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Aliqopa to treat gastric MALT lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma can be found in the NCCN Drugs and Biologics

Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VI. 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.