

**POLICY:** Oncology – Aliqopa™ (copanlisib injection for intravenous use – Bayer)

**APPROVAL DATE:** 09/04/2019

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### OVERVIEW

Aliqopa is an inhibitor of phosphatidylinositol-3-kinase (PI3K), particularly the PI3K- $\alpha$  and PI3K- $\delta$  isoforms found in malignant B cells.<sup>1</sup> Aliqopa inhibits cell-signaling pathways including B-cell receptor (BCR) signaling, CXCR12 mediated chemotaxis of malignant B-cells and K<sub>F</sub> $\kappa$ B signaling in lymphoma cell lines. Aliqopa induces tumor cell death by apoptosis and inhibits the proliferation of primary malignant B-cell lines.

Aliqopa is indicated for the treatment of adults with relapsed follicular lymphoma who have received at least two prior systemic therapies.<sup>1</sup> This indication was granted accelerated approval based on overall response rate. Continued approval may be dependent on verification and description of clinical benefit in a confirmatory trial.

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on B-Cell Lymphomas (version 4.2019 – June 18, 2019) recommend Aliqopa as a second-line or subsequent therapy for relapsed/refractory follicular lymphoma (grade 1 or 2), gastric and nongastric MALT, splenic marginal zone lymphoma, and nodal marginal zone lymphoma after  $\geq 2$  prior therapies.

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Aliqopa. Approval is recommended for those who meet the Criteria and Dosing for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Aliqopa, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Aliqopa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Aliqopa is recommended in those who meet one of the following criteria:

#### FDA-Approved Indications

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- 1. Follicular Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has received  $\geq 2$  prior systemic therapies. (NOTE: Examples of systemic therapies include bendamustine, cyclophosphamide, doxorubicin, vincristine, rituximab product [e.g., Rituxan, Truxima], Gazyva® [obinutuzumab injection for intravenous use]) ; AND
  - C) Aliqopa is prescribed by or in consultation with an oncologist.<sup>2,3</sup>

**Dosing.** Approve the following dosing regimen: Administer up to 60 mg intravenously, up to three times in each 28-day cycle.<sup>1</sup>

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### Other Uses with Supportive Evidence

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- 2. Marginal Zone Lymphoma (NOTE: Includes Gastric MALT, Nongastric MALT, Nodal Marginal Zone Lymphoma, and Splenic Marginal Zone Lymphoma).** Approve for 1 year if the patient meets the following criteria (A, B, and C):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has received  $\geq 2$  prior systemic therapies. (NOTE: Examples of systemic therapies include bendamustine, cyclophosphamide, doxorubicin, vincristine, rituximab product [e.g., Rituxan, Truxima], Gazyva<sup>®</sup> [obinutuzumab injection for intravenous use] ); AND
  - C) Aliqopa is prescribed by or in consultation with an oncologist.<sup>2,3</sup>

**Dosing.** Approve the following dosing regimen: Administer up to 60 mg intravenously, up to three times in each 28-day cycle.<sup>1</sup>

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### CONDITIONS NOT RECOMMENDED FOR APPROVAL

Aliqopa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

1. Aliqopa<sup>™</sup> injection for intravenous use [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; May 2019.
2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (Version 4.2019 – June 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed August 15, 2019.
3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 14, 2019. Search term: copanlisib.

### HISTORY

Type of Revision	Summary of Changes	Approval Date
New policy	--	09/19/2018
Annual	Increased approval duration to 1 year for all indications. Follicular Lymphoma: Removed Relapsed from the indication. Added Marginal Zone Lymphoma criteria. Removed Other Cancer Indications, and Waste Management sections.	09/04/2019