

**EFFECTIVE DATE:** 08|01|2019

**POLICY LAST UPDATED:** 04|16|2019

## OVERVIEW

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

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

## MEDICAL CRITERIA

Aliqopa™ (copanlisib) will be approved when ONE of the following are met:

1. There is documentation provided with the request (e.g. treatment start date, length of treatment, patient's clinical benefit from therapy) indicating that the patient is currently being treated with the requested agent

**OR**

2. ALL of the following:

- a. ONE of the following:

- i. The patient has an FDA labeled indication for the requested agent AND ALL of the following:

1. ONE of the following:

- a. The requested indication does NOT require genetic/specific diagnostic testing (e.g., ALK, EGFR, HER2, KRAS) in FDA labeling

**OR**

- b. The requested indication requires genetic/specific diagnostic testing in the FDA labeling AND ONE of the following:

- i. BOTH of the following

1. Genetic/diagnostic testing has been performed

**AND**

2. The results of the genetic/diagnostic testing indicate therapy with the requested agent is appropriate

**OR**

- ii. The requested indication does not require genetic/specific diagnostic testing in NCCN with level of evidence 1 or 2a

**AND**

2. ONE of the following:

- a. The requested agent is FDA labeled as a first-line agent for the requested indication

**OR**

- b. The patient has used the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling for the requested indication

**OR**

- c. The patient has used the appropriate number and type(s) of prerequisite agent(s) supported by NCCN 1 or 2A recommended use for the requested indication

**OR**

- d. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the required prerequisite agent(s) listed in the FDA labeling for the requested indication

**AND**

- 3. ONE of the following:

- a. The requested agent is approved for use as monotherapy in the FDA labeling for the requested indication

**OR**

- b. The requested agent will be used with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling for the requested indication

**OR**

- c. The requested agent will be used with all agent(s) and/or treatments supported in NCCN 1 or 2a recommended use for the requested indication

**AND**

- 4. ONE of the following:

- a. The FDA label does NOT include a performance status requirement

**OR**

- b. The patient meets the performance status requirement in the FDA labeling

**OR**

- ii. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™ [level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

**AND**

- b. The patient does NOT have any FDA labeled contraindications to the requested agent

**AND**

- c. The requested dose is within FDA labeling or dose and duration is supported by compendia. (NCCN Compendium™ [level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

**Length of Approval:** 12 months or for duration of treatment as supported in FDA labeling or NCCN compendia, whichever is shorter

#### **PRIOR AUTHORIZATION**

Prior authorization is required for BlueCHiP for Medicare.

#### **POLICY STATEMENT**

##### **BlueCHiP for Medicare**

Aliqopa™ (copanlisib) is medically necessary when the criteria above have been met.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug medically necessary benefits/coverage.

## BACKGROUND

Aliqopa (copanlisib) is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K- $\alpha$  and PI3K- $\delta$  isoforms expressed in malignant B cells. Copanlisib has been shown to induce tumor cell death by apoptosis and inhibition of proliferation of primary malignant B cell lines. Copanlisib inhibits several key cell-signaling pathways, including B-cell receptor (BCR) signaling, CXCR12 mediated chemotaxis of malignant B cells, and NF $\kappa$ B signaling in lymphoma cell lines.

## CODING

### BlueCHiP for Medicare

The following HCPCS code is covered when the medical criteria have been met:

**J9057** Injection, copanlisib, 1 mg

## RELATED POLICIES

Prior Authorization of Drugs

## PUBLISHED

Provider Update, June 2019

## REFERENCES

1. Aliqopa Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. September 2017.

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