

**CLINICAL GUIDELINES FOR MEDICAL NECESSITY**

**MEDICAL ONCOLOGY**

# Copanlisib (Aliqopa<sup>®</sup>)

Version: 1.0

**EFFECTIVE DATE: 1/1/2024**

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## Copanlisib (Aliqopa®)

**Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Please refer to the CMS website at <http://www.cms.gov> for additional information.**

**Note: For Medicaid members/enrollees, circumstances when state Medicaid coverage provisions conflict with the coverage provisions within this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.**

## Copanlisib (Aliqopa): Discussion

Copanlisib is a kinase inhibitor with activity predominantly against the 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. <sup>1</sup>

Copanlisib is a kinase inhibitor endorsed by the FDA and 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 the overall response rate.<sup>2</sup> The National Comprehensive Cancer Network (NCCN) endorses copanlisib in the following cancer types: B-cell lymphomas. <sup>3</sup>

## Copanlisib: Definitions

- **B-Cells** - A type of white blood cell that makes infection-fighting proteins called antibodies. B-cells are an important part of your immune system. <sup>4</sup>
- **Food and Drug Administration (FDA)** - The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- **National Comprehensive Cancer Network (NCCN)** - An alliance of thirty-two leading cancer centers devoted to patient care, research, and education. The NCCN guidelines are utilized for Radiation Therapy and Medical Oncology standards. NCCN consensus clinical standards are periodically updated and NantHealth, Inc. reviews these and updates its policies within a timely manner.
- **Phosphoinositide 3-kinases (PI3Ks)** - These are a family of enzymes involved in cellular functions such as cell growth, proliferation, differentiation, motility, survival, and intracellular trafficking, which in turn are involved in cancer. <sup>5</sup>

## Copanlisib: Policy

Copanlisib will be considered for coverage when the following criteria are met:

### B-cell Lymphomas

**(follicular lymphoma - grade 1-2, extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of non-gastric sites – non-cutaneous, nodal marginal zone lymphoma, and splenic marginal zone lymphoma)**

1. At least 18 years of age; AND
2. Prescribed by or in consultation with an oncologist; AND
3. Third line and subsequent therapy for relapsed, refractory, or progressive disease <sup>3</sup>

**Note:** Coverage of copanlisib will be provided for an FDA-approved indication or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1, 2A, or 2B recommendation or when all criteria are met.

## Authorization Period and Renewal Criteria

1. Initial Authorization Period: 12 months
2. Renewal Criteria: No evidence of disease progression or unacceptable toxicity
3. Renewal Authorization Period: 12 months

## Copanlisib: References

1. Aliqopa (copanlisib) Mechanism of Action. <https://www.centerwatch.com/directories/1067-fda-approved-drugs/listing/3117-aliqopa-copanlisib>. Accessed August 22, 2023.
2. Copanlisib (Aliqopa) [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2023/209936s011lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/209936s011lbl.pdf). Accessed August 22, 2023.
3. National Comprehensive Cancer Network Guidelines. B-Cell Lymphoma. (Version 5.2023). [https://www.nccn.org/professionals/physician\\_gls/pdf/b-cell.pdf](https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf). Accessed August 23, 2023.
4. B-Cells. <https://my.clevelandclinic.org/health/body/24669-b-cells>. Accessed August 23, 2023.
5. Molecular mechanism of activation of class IA phosphoinositide 3-kinases (PI3Ks) by membrane-localized HRas. <https://pubmed.ncbi.nlm.nih.gov/28515318>. Accessed August 23, 2023.

## Copanlisib: Coding (CPT®, ICD 10 and HCPCS) \*

\*Procedure codes appearing in medical policy documents are only included as a general reference. This list may not be all-inclusive and is subject to updates. In addition, the codes listed are not a guarantee of payment. CPT codes are available through the AMA.

CODE	DESCRIPTION
C82.9	Follicular lymphoma
C83.07	Splenic Marginal Zone Lymphoma
C88.4	Extranodal Marginal Zone Lymphoma
J9057	Copanlisib (Aliqopa)

## Copanlisib: Revision and Review History

NO.	DESCRIPTION	DATE(S)
1	Original Effective Date:	1/1/2024
2	Policy Review Dates:	10/2/2023
3	Policy Revision Dates:	
4	Department Owner:	Medical Affairs
5	NH Advisory Committee Approval Dates:	11/2/2023
6	Revision Changes:	