

# Medical Drug Clinical Criteria

**Subject:** Aliqopa (copanlisib)

**Document #:** CC-0133

**Publish Date:** 12/20/202412/21/2022

**Status:** ReviewedRevised

**Last Review Date:** 11/19/202411/18/2022

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## Overview

This document addresses the use of Aliqopa (copanlisib) injection. Aliqopa is a phosphatidylinositol-3-kinase (PI3K) inhibitor administered intravenously for the treatment of follicular lymphoma. The FDA approved indication for Aliqopa is for relapsed follicular lymphoma in those who have received at least two prior systemic therapies.

### Other Uses

The National Comprehensive Cancer Network (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Aliqopa in B-Cell Lymphomas including Gastric and Non-Gastric mucosa associated lymphoid tissue (MALT) Lymphoma, and Nodal and Splenic Marginal Zone Lymphoma (MZL). The evidence behind the MZL recommendation includes a subset analysis of the Phase II open-label, single-arm CHRONOS-1 Trial (Panayiotidis 2021). Within the subset of individuals with MZL (n=23), the objective response rate was 70%. Among the entire data set, the most common treatment-emergent adverse events included hyperglycemia, hypertension, diarrhea, fatigue, decreased neutrophil count, and fever. In April 2022, the FDA the Oncologic Drugs Advisory Committee (ODAC) met to discuss the Phosphatidylinositol 3-Kinase [PI3K] Inhibitors in Hematologic Malignancies. The committee voted in support of basing future approvals for PI3K inhibitors on randomized data instead of single arm clinical trials.

### Definitions and Measures

**Complete Response or Complete Remission (CR):** The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

**Disease Progression:** Cancer that continues to grow or spread.

**Follicular Lymphoma:** A type of B-cell non-Hodgkin lymphoma, a cancer of the immune system that is usually indolent (slow-growing). The tumor cells grow as groups to form nodules. There are several subtypes of follicular lymphoma.

**Partial response (PR):** A decrease in the size of a tumor, or in the amount of cancer in the body, resulting from treatment; also called partial remission.

**Refractory Disease:** Illness or disease that does not respond to treatment.

**Relapse or recurrence:** After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Aliqopa (copanlisib)

~~Initial~~ Requests for Aliqopa (copanlisib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of relapsed or refractory follicular lymphoma; **AND**
- II. Individual has received at least two prior systemic therapies; **AND**

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III. Individual has not had previous treatment with another PI3-kinase inhibitor (e.g. idelasib (Zydelig)).

Continuation of treatment requests for Aliqopa may be approved if the following criteria is met:

I. ~~Confirmation of continuing clinical benefit (e.g. complete response, partial response, or stable disease).~~

**Approval Duration:**

Initial and Maintenance Requests: 6 months

Requests for Aliqopa (copanlisib) may not be approved for the following:

- I. Individual is requesting for any other indication, including but not limited to when the criteria above have not been met; **OR**
- II. Repeat treatment after the development of disease progression or unacceptable toxicity.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

J9057 Injection, copanlisib, 1 mg [Aliqopa] [Note: code effective 01/01/2019; NOC codes J3590 or J9999 until 12/31/2018]

### ICD-10 Diagnosis

C82.00-C82.99 Follicular lymphoma

C83.00-C83.09 Small cell B-cell lymphoma

## Document History

Revised: 11/18/2022

Document History:

- 11/18/2022 – Annual Review: Remove continuation of use criteria for consistency. Coding Reviewed: No changes.
- 11/19/2021 – Annual Review: No changes. Coding reviewed: No changes.
- 11/20/2020 – Annual Review: No changes. Coding reviewed: No changes.
- 11/15/2019 – Annual Review: Remove age criteria; wording and formatting updates. Coding Review: No changes.
- 05/17/2019 – Annual Review: Initial review of Aliqopa (copanlisib). Wording and formatting changes. Coding reviewed: no changes.

## References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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