

Medical Drug Clinical Criteria

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| Subject: | Aliqopa (copanlisib) | | |
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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 original FDA approved indication for Aliqopa was for relapsed follicular lymphoma in those who have received at least two prior systemic therapies. The National Comprehensive Cancer Network (NCCN) provided additional recommendations with a category 2A level of evidence for the use of Aliqopa in marginal zone lymphoma (MZL). The three types of marginal zone lymphomas include extranodal MZLs, nodal MZL, and splenic MZL. In March of 2024, the FDA approval of Aliqopa was withdrawn because the required postmarketing trial did not verify the clinical benefit of Aliqopa for follicular lymphoma.

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)

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

- I. Individual has a diagnosis of one of the following:
 - A. Follicular lymphoma; **OR**
 - B. Splenic marginal zone lymphoma (NCCN 2A); **OR**
 - C. Nodal marginal zone lymphoma (NCCN 2A); **OR**
 - D. Extranodal marginal zone lymphoma of the stomach or of nongastric sites (NCCN 2A); **OR**
- II. Disease is relapsed, refractory, or progressive; **AND**
- III. Individual is using as third line of therapy or greater (Label/NCCN 2A); **AND**
- IV. Individual has not had previous treatment with another PI3-kinase inhibitor (e.g. idelasib (Zydelig)).

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

Reviewed: 11/15/2024

Document History:

- 11/15/2024 – Annual Review: No changes. Coding Reviewed: No changes.
- 11/17/2023 – Annual Review: Update criteria to include NCCN recommendations for additional types of B-cell lymphomas. Coding Reviewed: No changes.
- 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

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed August 27, 2024.
2. Dreyling M, Santoro A, Mollica L, et al. . Phosphatidylinositol 3-kinase inhibition by copanlisib in relapsed or refractory indolent lymphoma [published correction appears in J Clin Oncol. 2018;36(5):521]. J Clin Oncol. 2017;35(35):3898-3905.
3. Dreyling M, Panayiotidis P, Egyed M, et al. Efficacy of copanlisib monotherapy in patients with relapsed or refractory marginal zone lymphoma: subset analysis from the CHRONOS-1 trial [abstract]. Blood 2017; 130: Abstract 4053.
4. Panayiotidis P, Follows GA, Mollica L, et al. Efficacy and safety of copanlisib in patients with relapsed or refractory marginal zone lymphoma. *Blood Adv*. 2021;5(3):823-828. doi:10.1182/bloodadvances.2020002910.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.

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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