

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Aliqopa Prior Authorization Policy

- Aliqopa[®] (copanlisib intravenous infusion – Bayer)

REVIEW DATE: 09/04/2024

OVERVIEW

Aliqopa, a kinase inhibitor, is indicated for the treatment of relapsed **follicular lymphoma** in adults who have received at least two prior systemic therapies.¹

On November 13, 2023, Bayer announced that Aliqopa would be voluntarily withdrawn from the United States market after it failed to confirm the clinical benefit of Aliqopa in a confirmatory clinical trial.² Bayer recommended that no new patients be started on Aliqopa and patients currently receiving Aliqopa should consult their healthcare provider. Bayer is exploring options for patients deriving benefits from Aliqopa and for patients who have no other treatment options. The New Drug Application for Aliqopa was withdrawn by the FDA on March 18, 2024.³

Guidelines

The National Comprehensive Cancer Network guidelines on **B-Cell Lymphomas** (version 2.2024 – April 30, 2024) no longer recommend Aliqopa for the treatment of relapsed/refractory follicular lymphoma (grade 1 or 2), extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, splenic marginal zone lymphoma, and nodal marginal zone lymphoma.⁴

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Aliqopa. 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, approval requires Aliqopa to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

- 1. Follicular Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient is currently receiving Aliqopa; AND
 - C) Patient has received ≥ 2 prior systemic therapies; AND
Note: Examples of systemic therapies include bendamustine, cyclophosphamide, doxorubicin, vincristine, rituximab product (e.g., Rituxan, biosimilars), Gazyva (obinutuzumab intravenous infusion).
 - D) Aliqopa is prescribed by or in consultation with an oncologist.

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Other Uses with Supportive Evidence

2. **Marginal Zone Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

Note: This includes extranodal marginal zone lymphoma of the stomach, extranodal marginal zone lymphoma of nongastric sites, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.

- A) Patient is ≥ 18 years of age; AND
- B) Patient is currently receiving Aliqopa; AND
- C) Patient has received ≥ 2 prior systemic therapies; AND

Note: Examples of systemic therapies include bendamustine, cyclophosphamide, doxorubicin, vincristine, rituximab product (e.g., Rituxan, biosimilars), Gazyva (obinutuzumab intravenous infusion).

- D) Aliqopa is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Aliqopa is not recommended in the following situations:

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® intravenous infusion [prescribing information]. Whippany, NJ: Bayer; March 2023.
2. Bayer provides update on Aliqopa® (copanlisib) [press release]. Whippany, NJ: Bayer; Noember 13, 2023. Available at: <https://www.bayer.com/en/us/news-stories/update-on-aliqopar>. Accessed on August 28, 2024.
3. Bayer HealthCare Pharmaceuticals Inc.; Withdrawal of approval of new drug application for Aliqopa (copanlisib) for injection, 60 milligrams per vial. 89 F.R. 19327. Available at: <https://www.federalregister.gov/documents/2024/03/18/2024-05619/bayer-healthcare-pharmaceuticals-inc-withdrawal-of-approval-of-new-drug-application-for-aliqopa>. Accessed on August 28, 2024.
4. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – April 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 28, 2024.