CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Aliqopa Utilization Management Medical 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On November 13, 2023, Bayer announced that Aliqopa would be voluntarily withdrawn from the United States market after it failed to confirm the clinical benefit of Aliqopa in a confirmatory clinical trial.[2] Bayer recommended that no new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 The New Drug Application for Aliqopa was withdrawn by the FDA on March 18, 2024.[3]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 medical benefit coverage of Aliqopa. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). 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.

Dosing. Approve up to 60 mg administered intravenously up to three times in each 28-day cycle.

Other Uses with Supportive Evidence

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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.

Dosing. Approve up to 60 mg administered intravenously up to three times in each 28-day cycle.

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; September 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Marginal Zone Lymphoma:** Extranodal marginal zone lymphoma of the stomach and extranodal marginal zone lymphoma of nongastric sites added to the Note. Gastric mucosa associated lymphoid lymphoma (MALT) and nongastric MALT removed from the Note.	09/06/2023
Annual Revision	**Follicular Lymphoma:** Added requirement that the patient is currently receiving Aliqopa. **Marginal Zone Lymphoma:** Added requirement that the patient is currently receiving Aliqopa.	09/04/2024