Utilization Review Policy 147

POLICY: Oncology (Injectable) – Aliqopa
- Aliqopa™ (copanlisib intravenous infusion – Bayer)

EFFECTIVE DATE: 1/1/2021
LAST REVISION DATE: 09/06/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

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]

Guidelines
The National Comprehensive Cancer Network guidelines on **B-Cell Lymphomas** (version 5.2023 – July 7, 2023) recommend Aliqopa as a third-line agent and subsequent therapy for 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.[2,3]

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

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1. **Follicular Lymphoma.** Approve for 1 year if the patient meets the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** 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).
   - **C)** 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

2. Marginal Zone Lymphoma. Approve for 1 year if the patient meets the following (A, B, and C):
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 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).
C) 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; March 2023.
2. The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 5.2023 – July 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 30, 2023.
3. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 30, 2023. Search term: copanlisib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/07/2022
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