PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Aliqopa Prior Authorization Policy

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

REVIEW DATE: 09/07/2022

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network guidelines on **B-Cell Lymphomas** (version 5.2022 – July 12, 2022) recommend Aliqopa as third-line and subsequent therapy for relapsed/refractory follicular lymphoma (grade 1 or 2), gastric and nongastric mucosa-associated lymphoid tissue (MALT), splenic marginal zone lymphoma, and nodal marginal zone lymphoma after ≥ 2 prior therapies.^{2,3}

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 Aloqopa 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 the following criteria (A, B, and C):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has received ≥ 2 prior systemic therapies; AND <u>Note</u>: 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.

Other Uses with Supportive Evidence

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

<u>Note</u>: This includes gastric mucosa-associated lymphoid tissue (MALT), nongastric MALT, 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 <u>Note</u>: 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.

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; February 2022.
- The NCCN B-Cell Lymphoma Clinical Practice Guidelines in Oncology (version 5.2022 July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed August 30, 2022.
- 3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <u>http://www.nccn.org</u>. Accessed on August 30, 2022. Search term: copanlisib.