SmartHealth Ascension

Copanlisib

(Aliqopa®) J9057 (1mg)

Covered with prior authorization

Copanlisib (Aliqopa®) may be authorized when the following criteria are met:

- Individual has a diagnosis of relapsed or refractory follicular lymphoma; **AND**
- Individual has received at least two prior systemic therapies; **AND**
- Individual has not had previous treatment with another PI3-kinase inhibitor (e.g., idelasib (Zydelig).

OR

- Individual has a diagnosis of relapsed or refractory Marginal Zone Lymphoma
- Individual has received at least two prior systemic therapies

Exclusion Criteria:
Requests may not be approved for the following:

- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval is up to 6 months.

Reauthorization approval is up to 6 months.

Reauthorization Criteria:
Copanlisib is considered medically necessary for continued use when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Copanlisib (Aliqopa®) is a kinase inhibitor indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Aliqopa® [Prescribing Information]. Whippany, NJ: Bayer Healthcare PHarmaceuticals Inc.; 2022.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
4. NCCN Clinical Practice Guidelines in Oncology™. National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.