Clinical Policy: Copanlisib (Aliqopa)

Reference Number: PA.CP.PHAR.357
Effective Date: 10.17.17
Last Review Date: 10/30/2019

Revision Log

Description
Copanlisib (Aliqopa™) is a phosphatidylinositol-3-kinase inhibitor.

FDA Approved Indication(s)
Aliqopa is indicated for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies.*

**Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.*

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness that Aliqopa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Follicular Lymphoma (must meet all)**:**

1. Diagnosis of follicular lymphoma;
2. Age ≥ 18 years;
3. Member has received ≥ 2 prior systemic therapies (e.g., rituximab, obinutuzumab, doxorubicin, vincristine, alkylator therapy [e.g., bendamustine, chlorambucil, cyclophosphamide], idelalisib, lenalidomide);
4. Dose does not exceed 60 mg (1 vial) on Days 1, 8, and 15 of each 28-day treatment cycle.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Follicular Lymphoma (must meet all)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity);
3. If request is for a dose increase, new dose does not exceed 60 mg (1 vial) on Days 1, 8, and 15 of each 28-day treatment cycle.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PHAR.57 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Follicular lymphoma	60 mg IV on Days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (3 weeks on and 1 week off); modify for toxicity	60 mg/dose; 3 doses/28 day cycle

VI. Product Availability

Single-dose vial for injection: 60 mg as a lyophilized solid for reconstitution

VII. References

1. Aliqopa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2017. Available at: www.aliqopa.com. Accessed September 18, 2017.
2. Copanlisib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed September 26, 2017.
3. National Comprehensive Cancer Network. B-cell Lymphomas Version 5.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed September 26, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	07/18/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01/01/2020	07/17/19	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/30/19	