Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2022**
Policy Number: PA.CP.PHAR.357	**Effective Date: 10/2017** **Revision Date: 10/2022**
Policy Name: Copanlisib (Aliqopa)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

4Q 2022 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Copanlisib (Aliqopa)

Reference Number: PA.CP.PHAR.357
Effective Date: 10/2017
Last Review Date: 10/2022

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 (FL) 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 PA Health & Wellness that Aliqopa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Follicular and Other B-Cell Lymphomas (must meet all)**:**

1. Diagnosis of one of the following B-cell lymphoma subtypes (a or b):
   a. FL;
   b. Marginal zone lymphoma (off-label) (i, ii, or iii):
      i. Splenic marginal zone lymphoma;
      ii. Nodal marginal zone lymphoma;
      iii. Extranodal marginal zone lymphoma (a or b):
         a) Gastric MALT lymphoma;
         b) Nongastric MALT lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Relapsed/progressive/refractory disease after ≥ 2 prior therapies (*see Appendix B for examples*);*
   **Prior authorization may be required*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 60 mg (1 vial) per week for 3 out of 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Follicular and Other B-Cell Lymphomas (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;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 60 mg (1 vial) per week for 3 out of 4 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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.PMN.53 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.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
FL: follicular lymphoma
NCCN: National Comprehensive Cancer Network

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Follicular Lymphoma *Examples of first-line, second-line and subsequent therapies:* • bendamustine + Gazyva® (obinutuzumab) or rituximab • CHOP (cyclophosphamide, doxorubicin, vincristine, predenisone) + Gazyva or rituximab • CVP (cyclophosphamide, vincristine, prednisone) + Gazyva or rituximab	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
• Single-agent examples: rituximab; Revlimid® (lenalidomide) ± rituximab		
Marginal Zone Lymphomas *Examples of first-line, second-line and subsequent therapies:* • bendamustine + rituximab, bendamustine + Gazyva® • RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • RCVP (rituximab, cyclophosphamide, vincristine, prednisone) • Single-agent examples: rituximab; Leukeran® (chlorambucil) ± rituximab; cyclophosphamide ± rituximab; Imbruvica® (ibrutinib); Revlimid ± rituximab; Copiktra® (duvelisib); Zydelig® (idelalisib)	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

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

VI. Product Availability

Single-dose vial: 60 mg

VII. References

1. Aliqopa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; January 2022. Available at: www.aliqopa.com. Accessed August 2, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed August 2, 2022.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 5.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. August 2, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9057	Injection, copanlisib, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	07/2018	
3Q 2019 annual review: No changes per Statewide PDL implementation 01/01/2020	07/2019	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: NCCN recommended B-cell lymphoma subtypes added - Appendix B required therapy examples expanded accordingly; relapsed or refractory disease added; dosing detail - 3 out of 4 weeks - added per PI; FDA/NCCN dosing limitation added; references reviewed and updated.	10/2020	
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021	
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022	