Clinical Policy Title:	copanlisib
Policy Number:	RxA.011
Drug(s) Applied:	Aliqopa®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Copanlisib is a phosphatidylinositol-3-kinase inhibitor that is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) in non-Hodgkin's lymphoma (NHL) who have received at least two (2) 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.*

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
copanlisib (Aliqopa®)	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

Dosage Forms

- Single-dose vial: 60 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Follicular and other B-Cell Lymphomas (must see all):

1. Member has a diagnosis of one of the following B-cell lymphoma subtypes (a or b):
   a. Follicular lymphoma;
   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) Non-gastric MALT lymphoma;
2. Disease is relapsed or refractory;
3. Prescribed by or in consultation with an oncologist or hematologist;

4. Member is 18 years of age or older;
5. Member has received at least two (2) prior systemic therapies prior to copanlisib (*see examples at Appendix B*);
   **Prior authorization may be required for systemic therapies.*
6. 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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 • Single-agent examples: rituximab; Revlimid® (lenalidomide) ± rituximab	Varies	Varies
Marginal Zone Lymphomas *Examples of first-line, second-line and subsequent therapies:* • bendamustine + rituximab • 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

- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information

- Reduce the dose to 45mg in patients with moderate hepatic impairment (Child-Pugh B).

References

1. Aliqopa® Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2020. Available at: http://labeling.bayerhealthcare.com/html/products/pi/Aliqopa_PI.pdf. Accessed January 20, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed January 20, 2021.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed January 20, 2021.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;2020. Available at: http://clinicalpharmacology-ip.com/. Accessed January 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy reviewed and updated. 1. Updated References 2. Updated indication to include non-Hodgkin's lymphoma 3. Added general information	05/2020	05/21/2020
Policy reviewed and updated. 1. Clinical policy title and lines of busines updated. 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 3. References updated.	01/20/2021	03/09/2021