Clinical Policy Title:	copanlisib
Policy Number:	RxA.011
Drug(s) Applied:	Aliqopa®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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. Extra-nodal 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. Age ≥ 18 years;
5. Member has received at least two (2) prior systemic therapies prior to copanlisib;
   *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 the member has 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. 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

References

1. National Comprehensive Cancer Network. B-Cell Lymphomas Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 04, 2022.

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.	05/2020	05/21/2020
Policy reviewed and updated. 1. Clinical policy title and lines of business 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
Policy reviewed and updated. 1. References were reviewed and updated.	11/18/2021	01/17/2022
Policy reviewed and updated. 1. References were reviewed and updated.	07/04/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023