

Clinical Policy: Copanlisib (Aliqopa)

Reference Number: CP.PHAR.357

Effective Date: 10.17.17

Last Review Date: 11.18

Line of Business: Medicaid, HIM-Medical Benefit

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

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

It is the policy of health plans affiliated with Centene Corporation® that Aliqopa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria**A. Follicular Lymphoma** (must meet all):

1. Diagnosis of FL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. Member has received \geq 2 prior systemic therapies (e.g., Rituxan®, Gazyva®, doxorubicin, vincristine, alkylator therapy [e.g., bendamustine, Leukeran®, cyclophosphamide], Zydelig®, Revlimid®);
**Prior authorization is (or may be) required for Rituxan, Gazyva, vincristine, bendamustine, Zydelig, and Revlimid*
5. Dose does not exceed 60 mg (1 vial) per week.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy**A. Follicular Lymphoma** (must meet all):

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1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Aliqopa for FL and has received this medication for at least 30 days;
 2. Member is responding positively to therapy;
 3. If request is for a dose increase, new dose does not exceed 60 mg (1 vial) per week.
- Approval duration: 12 months**

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

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 – HIM.PHAR.21 for health insurance marketplace and 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

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
Rituxan (rituximab)	375 mg/m ² IV weekly (alone or as part of a chemotherapy regimen)	375 mg/m ² /week
Zydelig (idelalisib)	150 mg PO BID	300 mg/day
Gazyva (obinutuzumab), doxorubicin (Adriamycin®), vincristine (Vincasar®), bendamustine (Treanda®), Bendeka®, Leukeran (chlorambucil), Revlimid (lenalidomide)	Various combination regimens (e.g., CHOP, RCHOP, CVP, RCVP)	Varies

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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 and 1 week off)	60 mg/dose/week

VI. Product Availability

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

VII. References

1. Aliqopa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; September 2017. Available at: www.aliqopa.com. Accessed July 26, 2018.
2. Copanlisib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed July 26, 2018.
3. National Comprehensive Cancer Network. B-cell Lymphomas Version 4.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed July 26, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.17.17	11.17
4Q 2018 annual review: no significant changes; HIM-Medical added specialist prescriber requirement; references reviewed and updated.	07.26.18	11.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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