

# Copanlisib (Aliqopa®) Criteria for Use August 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive copanlisib.

- Care not provided by a VA/VA Community Care hematology/oncology provider
- CrCl <15 mL/minute
- Severe hepatic impairment (Child-Pugh class C or total bilirubin 3 to 10x ULN)
- Patients receiving concomitant therapy with strong CYP3A inducers
- Uncontrolled hypertension with blood pressure  $\geq$  150/90 mmHg despite optimal medical management
- History or concurrent condition of interstitial lung disease
- Ongoing or active systemic infection, including hepatitis B or C or known HIV
- Pregnancy
- Breastfeeding

## Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria:

- Diagnosis of follicular lymphoma
- Relapsed or refractory disease after  $\geq$  2 prior lines of therapy. Patients must have received rituximab and alkylating agents (unless contraindicated)
- ECOG performance status 0, 1 or 2
- Patients with diabetes mellitus are willing and able to have close monitoring due to risk of hyperglycemia

For women of childbearing potential:

- Pregnancy should be excluded prior to receiving copanlisib and the patient provided contraceptive counseling on potential risks vs. benefits of taking copanlisib if patient were to become pregnant. Advise that highly effective contraception should be used during treatment with copanlisib and for at least one month after the last dose.

For men with partners of childbearing potential:

- Advise that highly effective contraception should be used during treatment with copanlisib and for at least one month after the last dose.