Acalabrutinib tablet (CALQUENCE)
Criteria for Use
December 2024

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 S HOULD 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 acalabrutinib.

- ☐ Patient has not been screened for Hepatitis B Virus (HBV).
- ☐ Unmanageable drug-drug interaction identified
- ☐ History of stroke or intracranial hemorrhage in prior 6 months
- ☐ Clinically significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, congestive heart failure (NYHA Class 3 or 4), or myocardial infarction in prior 6 months
- ☐ Active or uncontrolled infection
- ☐ Severe hepatic impairment (Child-Pugh C), as drug has not been evaluated in this population
- ☐ Known pregnancy
- ☐ Lactating

Inclusion Criteria

One of the following criteria must be met:

- ☐ Mantle Cell Lymphoma (MCL) and progressive disease or intolerance to at least one prior therapy
- ☐ Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

  Note: Acalabrutinib is not effective in the setting of the BTK^{C481S} mutation that confers resistance to ibrutinib

Additional Inclusion Criteria

All of the following must be fulfilled in order to meet criteria:

- ☐ Care provided by a VA/VA Community Care hematology/oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented.
- ☐ Eastern Cooperative Oncology Group Performance Status 0-2

Additional Inclusion Criteria *Select if applicable:*

- ☐ For females who can become pregnant: Counseling on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for at least one week after the last dose
- ☐ Advise females not to breastfeed during treatment and for at least 2 weeks after the last dose

Other Justification

- ☐

Prepared: February 2019; updated August 2020, September 2022, Dec 2024. Contact person: Berni Heron, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services