

Reference number(s)
2397-A

## SPECIALTY GUIDELINE MANAGEMENT

### CALQUENCE (acalabrutinib)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Calquence is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

B. Compendial Use

Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), relapsed or refractory

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: For ibrutinib-refractory CLL/SLL, BTK C481S mutation status

##### III. CRITERIA FOR INITIAL APPROVAL

A. **Mantle cell lymphoma**

Authorization of 12 months may be granted for treatment of mantle cell lymphoma when the member has received at least one prior therapy.

B. **Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)**

Authorization of 12 months may be granted for treatment of relapsed or refractory CLL/SLL when the member does not have ibrutinib (Imbruvica)-refractory disease with BTK C481S mutation.

##### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity.

##### V. REFERENCES

1. Calquence [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2017.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2019.

Reference number(s)
2397-A

3. The NCCN Clinical Practice Guidelines in Oncology® B-Cell Lymphomas Version 2.2019. National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 7, 2019.
4. The NCCN Clinical Practice Guidelines in Oncology® Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 4.2019. National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed March 17, 2019.