

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Calquence® (acalabrutinib capsules – AstraZeneca)

**DATE REVIEWED:** 06/05/2019; selected revision 12/04/2019

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### OVERVIEW

Calquence is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy.<sup>1</sup> Calquence is also indicated for the treatment of adults with chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL).

### Disease Overview

Mantle cell lymphoma is a rare and fast-growing type of non-Hodgkin lymphoma (NHL).<sup>3</sup> It accounts for approximately 6% of cases of newly-diagnosed NHL. The median age at diagnosis is 68 years of age and it is more common in males. Mantle cell lymphoma is a cancer involving the lymphatic system which is part of the immune system comprised of lymph tissue, lymph nodes, the spleen, thymus, tonsils, and bone marrow. Approximately one-third of patients with mantle cell lymphoma present with high levels of lactate dehydrogenase (LDH).

CLL is one of the most prevalent adult leukemias in the Western world.<sup>4</sup> In 2019, an estimated 20,720 patients will be diagnosed with CLL in the US, and approximately 3,930 patients will die from the disease. The condition usually is diagnosed in older adults ( $\geq 70$  years of age) and occurs more frequently in men. The leukemic cells appear as small, mature lymphocytes. CLL and SLL are different manifestations of the same condition and are managed similarly. In CLL, many of the abnormal lymphocytes are found in the blood, as well as in the bone marrow and lymphoid tissue. In SLL, there are few, if any, abnormal lymphocytes circulating in blood and most of the disease is in the lymph nodes, bone marrow, and other lymphoid tissue. The diagnosis requires the presence of at least  $5 \times 10^9/L$  monoclonal B-lymphocytes in the peripheral blood. SLL requires the presence of lymphadenopathy and/or splenomegaly with  $< 5 \times 10^9/L$  B-lymphocytes found in the peripheral blood.

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for B-cell lymphomas (version 3.2019 – May 6, 2019) provide recommendations for patients with mantle cell lymphoma.<sup>3</sup> Various agents and chemotherapy regimens are recommended, many of which are given intravenously (IV) and involve Rituxan® (rituximab injection for IV use) therapy. Calquence is recommended as a preferred agent as second-line therapy.

The NCCN guidelines for CLL/small lymphocytic lymphoma (SLL) [version 2.2020 – October 8, 2019] list Calquence as a preferred option (category 1) for relapsed/refractory therapy for both patients with and without del(17p)/TP53 mutation.<sup>4</sup>

### POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Calquence. All approvals are provided for the duration noted below.

**Automation:** None.

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### **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Calquence is recommended in those who meet the following criteria:

#### **FDA-Approved Indications**

- 1. Mantle Cell Lymphoma.** Approve for 3 years.
- 2. Chronic Lymphocytic Leukemia (CLL).** Approve for 3 years.
- 3. Small Lymphocytic Lymphoma (SLL).** Approve for 3 years.

#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Calquence has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

1. Calquence® capsules [prescribing information]. Wilmington, DE: AstraZeneca; November 2019.
2. Wang M, Rule S, Zinzani PF, et al. Acalabrutinib in relapsed or refractory mantle cell lymphoma (ACE-LY-004): a single-arm, multicenter, phase 2 trial. *Lancet*. 2018;391(10121):659-667.
3. The NCCN B-cell Lymphomas Guidelines in Oncology (Version 3.2019 – May 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on May 31, 2019.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2020 – October 8, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at <http://www.nccn.org>. Accessed on December 2, 2019.

**HISTORY**

Type of Revision	Summary of Changes*	Date Reviewed
New Policy	-	11/01/2017
Early Annual revision	Changed the criteria for Calquence regarding mantle cell lymphoma from requiring a trial of one other therapy to approve the requests. Criteria added in other uses with supportive evidence section to approve Calquence for chronic lymphocytic leukemia and small lymphocytic lymphoma if the patient has tried one other therapy (as recommended in NCCN guidelines).	05/16/2018
Annual revision	For clarity, the reference to Rituxan when listing previous required therapies was changed to “rituximab”. Also, the following changes were also made: 1. Chronic Lymphocytic Leukemia: Venclexta plus Gazyva and Copiktra were added to the list of examples of agents that count toward the requirement of a trial of one prior therapy. 2. Small Lymphocytic Lymphoma: Venclexta plus Gazyva and Copiktra were added to the list of examples of agents that count toward the requirement of a trial of one prior therapy.	06/05/2019
Selected revision	The indications of chronic lymphocytic leukemia and small lymphocytic lymphoma were moved from the Other Uses with Supportive Evidence section to the FDA-Approved Indications section. Also, the criteria were revised to approve for these indications and a trial of one prior therapy is no longer required.	12/4/2019

NCCN – National Comprehensive Cancer Network.