

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Calquence Prior Authorization Policy

- Calquence® (acalabrutinib capsules and tablets – AstraZeneca)

**REVIEW DATE:** 07/13/2022; selected revision 08/17/2022

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### OVERVIEW

Calquence, a Bruton tyrosine kinase (BTK) inhibitor, is indicated in adults for the following uses:<sup>1,2</sup>

- **Chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL).**
- **Mantle cell lymphoma**, in patients who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

### Guidelines

Calquence is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **B-Cell Lymphomas:** NCCN guidelines (version 4.2022 – June 9, 2022) address mantle cell lymphoma and marginal zone lymphoma.<sup>3,6</sup> Calquence is recommended as one of several preferred agents as second-line and subsequent therapy for mantle cell lymphoma (category 2A); there is a footnote that states that Calquence has not been shown to be effective for Imbruvica® (ibrutinib tablets or capsules)-refractory mantle cell lymphoma with *BTK* C481S mutations. Patients with Imbruvica intolerance have been successfully treated with Calquence or Brukinsa® (zanubrutinib capsules) without recurrence of symptoms. For marginal zone lymphoma, the NCCN guidelines indicate to consider Calquence as an alternative BTK inhibitor for second-line and subsequent therapy for relapsed or progressive disease in patients who are intolerant to or have contraindications to Imbruvica (category 2A).
- **CLL/SLL:** NCCN guidelines (version 3.2022 – June 3, 2022) list Calquence as a preferred first-line therapy option as a single agent or in combination with Gazyva® (obinutuzumab intravenous infusion) for patients with deletion(17p)/TP53 mutation (category 2A) or without deletion(17p)/TP53 mutation (category 1).<sup>4,6</sup> The guidelines also list single-agent Calquence as a preferred second-line and subsequent therapy for patients with or without deletion(17p)/TP53 mutation (category 1); there is a footnote that states that Calquence has not been shown to be effective for Imbruvica-refractory CLL with *BTK* C481S mutations. Patients with Imbruvica intolerance have been successfully treated with Calquence or Brukinsa without recurrence of symptoms.
- **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 1.2023 – July 6, 2022) recommend single-agent Calquence as an Other Recommended Regimen for previously treated disease (category 2A).<sup>5,6</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 one of the following criteria:

### FDA-Approved Indications

- 1. Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient is  $\geq 18$  years of age.
- 2. Mantle Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has tried at least one systemic regimen.  
Note: Examples of a systemic regimen contain one or more of the following products: rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, lenalidomide, or Imbruvica (ibrutinib tablets and capsules).
- 3. Small Lymphocytic Lymphoma.** Approve for 1 year if the patient is  $\geq 18$  years of age.

### Other Uses with Supportive Evidence

- 4. Marginal Zone Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):  
Note: Marginal zone lymphoma includes gastric mucosa-associated lymphoid tissue (MALT) lymphoma, non-gastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma.
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has tried at least one systemic regimen; AND  
Note: Examples of a systemic regimen contain one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, Gazyva (obinutuzumab intravenous infusion), or Imbruvica (ibrutinib tablets and capsules).
  - C) According to the prescriber, the patient has intolerance or contraindication to Imbruvica (ibrutinib tablets and capsules).
- 5. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has tried at least one systemic regimen.  
Note: Examples of a systemic regimen contain one or more of the following products: Brukinsa (zanubrutinib capsules), Imbruvica (ibrutinib tablets and capsules), rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Calquence is not recommended in the following situations:

- 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. Calquence® tablets [prescribing information]. Wilmington, DE: AstraZeneca; August 2022.
3. The NCCN B-Cell Lymphomas Guidelines in Oncology (version 4.2022 – June 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 11, 2022.
4. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2022 – June 3, 2022). © 2022 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. Accessed on July 11, 2022.
5. The NCCN Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2023 – July 6, 2022). © 2022 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. Accessed on July 11, 2022.
6. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 11, 2022. Search term: acalabrutinib.