VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Bruton's Tyrosine Kinase Inhibitor) – Calquence Prior Authorization Policy
- Calquence® (acalabrutinib tablets – AstraZeneca)

REVIEW DATE: 06/12/2024

OVERVIEW

Calquence, a Bruton tyrosine kinase (BTK) inhibitor, is indicated in adults for the following uses:[1]

- **Chronic lymphocytic leukemia (CLL) or small lymphocytic leukemia (SLL)**.
- **Mantle cell lymphoma**, previously untreated, in combination with bendamustine and rituximab in patients who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
- **Mantle cell lymphoma**, in patients who have received at least one prior therapy.

Guidelines

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

- **B-Cell Lymphomas**: NCCN guidelines (version 1.2025 – December 20, 2024) address mantle cell lymphoma and marginal zone lymphoma.[2,5] 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, capsules, or oral solution)-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. Calquence can also be used in combination with rituximab as pre-treatment in order to limit the number of cycles of aggressive induction therapy with RHyperCVAD (rituximab, cyclophosphamide, vincristine, doxorubicin, and dexamethasone) regimen (category 2A). Calquence is also recommended as "preferred" aggressive induction therapy (category 2B), "preferred" less aggressive induction therapy in combination with rituximab (category 2A), and maintenance therapy with chemotherapy (category 2B). For marginal zone lymphoma, NCCN guidelines recommend Calquence as a "preferred" regimen for second-line and subsequent therapy including patients who are older or infirm (category 2A).
- **CLL/SLL**: NCCN guidelines (version 3.2024 – March 26, 2024) 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).[3,5] The guidelines also list single-agent Calquence as a "preferred" second-line or third-line 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.
- **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 2.2024 – December 5, 2023) recommend single-agent Calquence as "Other Recommended Regimen" for previously treated disease (category 2A).[4,5]

POLICY STATEMENT

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

Automation: None.

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 ≥ 18 years of age.

2. **Mantle Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets ONE of the following (a or b):
       - **a)** Patient has tried at least one systemic regimen; OR
         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, or lenalidomide.
       - **b)** According to the prescriber, patient is not a candidate for a systemic regimen (i.e., an elderly person who is frail); OR
     - **ii.** Calquence is used in combination with rituximab.

3. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses with Supportive Evidence

4. **Marginal Zone Lymphoma**. Approve for 1 year if the patient meets BOTH of the following (A and B):
   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 ≥ 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: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil.

5. **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 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, capsules, and oral solution), 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 ® tablets [prescribing information]. Wilmington, DE: AstraZeneca; January 2025.
2. The NCCN B-Cell Lymphomas Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 17, 2025.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – March 26, 2024). © 2024 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on June 7, 2024.
4. The NCCN Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 2.2024 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on June 7, 2024.
5. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 7, 2024. Search term: acalabrutinib.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	07/12/2023
Annual Revision	**Mantle Cell Lymphoma**: Criterion which states "Calquence is used in combination with rituximab" was added as an option for approval.	06/12/2024
Update	**01/17/2025**: The overview section was updated to include new FDA approved indication of Previously untreated mantle cell lymphoma, in combination with bendamustine and rituximab in patients who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).	--
Update	04/08/2025: The policy name was changed from "Oncology – Calquence PA Policy" to "Oncology (Oral - Bruton's Tyrosine Kinase Inhibitor) – Calquence PA Policy".	N/A