VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Calquence Prior Authorization Policy
- Calquence® (acalabrutinib capsules – AstraZeneca)

REVIEW DATE: 06/30/2021

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**, 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**: [2,5] NCCN guidelines (version 4.2021 – May 5, 2021) address mantle cell lymphoma and marginal zone lymphoma. Calquence is recommended as one of several preferred agents as second-line and subsequent therapy for mantle cell lymphoma (category 2A). 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® (ibrutinib tablets or capsules) [category 2A].
- **CLL/SLL**:[3,5] NCCN guidelines (version 4.2021 – April 29, 2021) list Calquence as a preferred first-line therapy option as a single agent or in combination with Gazyva® (obinutuzumab intravenous infusion) for patients with or without del(17p)/TP53 mutation. The guidelines also list single-agent Calquence as a preferred second-line and subsequent therapy for patients with or without del(17p)/TP53 mutation.
- **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma:** NCCN guidelines (version 1.2022 – June 24, 2021) recommend single-agent Calquence as an 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 the following criteria:

FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia.** Approve for 3 years if the patient is ≥ 18 years of age.

2. **Mantle Cell Lymphoma.** Approve for 3 years if the patient meets the following criteria (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: rituximab, dexamethasone, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, Velcade (bortezomib injection), Revlimid (lenalidomide capsules), Imbruvica (ibrutinib capsule and tablet), or Calquence (acalabrutinib capsule).

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

Other Uses with Supportive Evidence

4. **Marginal Zone Lymphoma**. Approve for 3 years if the patient meets the following criteria (A, B, and C):
   Note: Marginal zone lymphoma includes gastric 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; AND
   Note: Examples of a systemic regimen contain one or more of the following products: bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, Revlimid (lenalidomide capsules), Gazyva (obinutuzumab intravenous infusion), or Imbruvica (ibrutinib tablets and capsules).
   C) According to the prescriber, the patient has intolerance or contraindication to Imbruvica (ibrutinib capsule or tablet).

5. **Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma.** Approve for 3 years if the patient meets the following criteria (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 and capsules), rituximab, bendamustine, cyclophosphamide, dexamethasone, Velcade (bortezomib injection), 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. The NCCN B-cell Lymphomas Guidelines in Oncology (version 4.2021 – May 5, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on June 6, 2021.
3. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (Version 4.2021 – April 29, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed on June 9, 2021.
4. The NCCN Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2022 – June 24, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at http://www.nccn.org. Accessed on June 29 , 2021.
5. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 24, 2021. Search term: acalabrutinib.