BlueCross BlueShield Federal Employee Program

CALQUENCE (acalabrutinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Calquence (acalabrutinib) is a small-molecule inhibitor of Bruton tyrosine kinase (BTK). Calquence and its active metabolite, ACP-5862, form a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B cell antigen receptor (BCR) and cytokine receptor pathways. In B cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. As a result of BTK inhibition, Calquence inhibits malignant B-cell proliferation and tumor growth (1-2).

Regulatory Status

FDA-approved indications: Calquence is a kinase inhibitor indicated: (1-2)

- In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous hematopoietic stem cell transplantation (HSCT).
- For the treatment of adult patients with MCL who have received at least one prior therapy.
- For the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Calquence used in combination with obinutuzumab is only indicated for previously untreated CLL or SLL (1-2).

Patients have a chance of Grade 3 or higher bleeding events (subdural hematoma, gastrointestinal bleeding, and hematuria). Calquence may increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies. Consider the benefit-risk of withholding Calquence for at least 3 to 7 days pre and post-surgery depending upon the type of surgery and the risk of bleeding (1-2).

Significant adverse reactions may occur with Calquence therapy including fatal and non-fatal infections, atrial fibrillation, atrial flutter, cytopenias, myelosuppression and primary malignancies including skin cancers. Patients should have the following monitored while on Calquence therapy: fever, infections, complete blood counts, and hydration (1-2).

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Based on findings in animals, Calquence may cause fetal harm when administered to a pregnant woman (1-2).

The safety and effectiveness of Calquence in pediatric patients less than 18 years of age have not been established (1-2).

Summary

Calquence (acalabrutinib) is a small-molecule inhibitor of BTK. Calquence and its active metabolite, ACP-5862, form a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B cell antigen receptor (BCR) and cytokine receptor pathways. In B cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. As a result of BTK inhibition, Calquence inhibits malignant B-cell proliferation and tumor growth. The safety and effectiveness of Calquence in pediatric patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Calquence while maintaining optimal therapeutic outcomes.

References

1. Calquence capsules [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2025.
2. Calquence tablets [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2025.
3. NCCN Drugs & Biologics Compendium® Acalabrutinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.