

**JAYPIRCA
(pirtobrutinib)****RATIONALE FOR INCLUSION IN PA PROGRAM****Background**

Jaypirca (pirtobrutinib) is a small molecule, noncovalent inhibitor of Bruton's tyrosine kinase (BTK) and cytokine receptor pathways. In B-cells, BTK signaling results in activation of pathways necessary for B-cell proliferation, trafficking, chemotaxis, and adhesion. Jaypirca binds to wild type BTK and BTK harboring C481 mutations, leading to inhibition of BTK kinase activity. Jaypirca inhibits BTK-mediated B-cell CD69 expression and inhibits malignant B-cell proliferation (1).

Regulatory Status

FDA-approved indications: Jaypirca is a kinase inhibitor indicated for the treatment of (1):

1. Adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor.
2. Adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.

Jaypirca contains warnings regarding the following: infections, hemorrhage, cytopenias, cardiac arrhythmias including atrial fibrillation and atrial flutter, second primary malignancies, and hepatotoxicity including drug-induced liver injury (1).

Jaypirca can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Jaypirca and for one week after the last dose (1).

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

.

Summary

Jaypirca (pirtobrutinib) is a BTK inhibitor indicated for the treatment of relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor and for the treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma



Federal Employee Program.

JAYPIRCA (pirtobrutinib)

(CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. Jaypirca contains warnings regarding infections, hemorrhages, and cytopenias, among others. The safety and effectiveness of Jaypirca in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Jaypirca [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2024.
2. NCCN Drugs & Biologics Compendium[®] Pirtobrutinib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 15, 2025.