BlueCross BlueShield Federal Employee Program

COPIKTRA (duvelisib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Copiktra (duvelisib) is an inhibitor of phosphatidylinositol 3-kinase (PI3K) with inhibitory activity predominantly against PI3K-delta and PI3K-gamma isoforms expressed in normal and malignant B-cells. Copiktra induced growth inhibition and reduced viability in cell lines derived from malignant B-cells and in primary chronic lymphocytic leukemia (CLL) tumor cells. Copiktra inhibits several key cell-signaling pathways, including B-cell receptor signaling and CXCR12-mediated chemotaxis of malignant B-cells. Additionally, Copiktra inhibits CXLCL12-induced T cell migration and M-CSF and IL-4 driven M2 polarization of macrophages (1).

Regulatory Status

FDA-approved indications: Copiktra is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior lines of systemic therapies (1).

Limitations of use: Copiktra is not indicated or recommended for the treatment of any patients with CLL or SLL as initial or second line treatment due to an increased risk of treatment-related mortality (1).

Off-Label Uses: (2)

1. Breast implant-associated anaplastic large cell lymphoma (ALCL)
2. Hepatosplenic T-Cell lymphoma
3. Peripheral T-Cell lymphomas (PTCL)

Copiktra has boxed warnings for treatment-related mortality, serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis. Copiktra should be withheld if any of serious toxicities occur. The most common serious infections were pneumonia, sepsis, and lower respiratory infections. Patients should be advised to report and new or worsening diarrhea. Presenting features for serious cutaneous reactions were primarily described as pruritic, erythematous, or maculo-papular. Patients should be monitored for pulmonary symptoms and interstitial infiltrates (1).

Additional warnings for Copiktra include hepatotoxicity, neutropenia, and embryo-fetal toxicity.

Hepatic function and blood counts should be monitored, and patients should be advised of potential risk to a fetus and use effective contraception (1).

Prophylaxis for *Pneumocystis jirovecii* (PJP) should be provided during treatment with Copiktra. Following completion of Copiktra treatment, PJP prophylaxis should be continued until the absolute CD4+ T cell count is greater than 200 cells/µL. Copiktra should be withheld in patients with suspected PJP of any grade and discontinued if PJP is confirmed. Prophylactic antivirals should also be considered to prevent cytomegalovirus (CMV) infection including CMV reactivation (1).

The safety and effectiveness of Copiktra in pediatric patients have not been established (1).

Summary

Copiktra (duvelisib) is a kinase inhibitor used to treat a variety of cancers. Copiktra carries boxed warnings regarding serious toxicities including infections, diarrhea or colitis, cutaneous reactions, and pneumonitis. Patients should also receive prophylaxis for *Pneumocystis jirovecii* (PJP) during treatment with Copiktra. The safety and effectiveness of Copiktra in pediatric patients have not been established (1).

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

References

1. Copiktra [package insert]. Las Vegas, NV: Secura Bio; July 2024.
2. NCCN Drugs & Biologics Compendium® Duvelisib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2025.