



5.21.116

Section:	Prescription Drugs	Effective Date:	April 1, 2025
Subsection:	Antineoplastic Agents	Original Policy Date:	October 12, 2018
Subject:	Copiktra	Page:	1 of 5

Last Review Date: March 7, 2025

Copiktra

Description

Copiktra (duvelisib)

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 CXCL12-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)

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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/ μ L. 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).

Related policies

Zydelig

[Policy](#)

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Copiktra may be considered **medically necessary** if the conditions indicated below are met.

Copiktra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

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Patient must have **ONE** of the following:

1. Relapsed or refractory chronic lymphocytic leukemia (CLL)
 - a. Patient has had at least **TWO** prior lines of systemic therapies
2. Relapsed or refractory small lymphocytic lymphoma (SLL)
 - a. Patient has had at least **TWO** prior lines of systemic therapies
3. Breast implant-associated anaplastic large cell lymphoma (ALCL)
4. Hepatosplenic T-Cell lymphoma
5. Peripheral T-Cell lymphoma (PTCL)

AND ALL of the following:

1. Prescriber agrees to monitor for serious toxicities including infections, diarrhea or colitis, cutaneous reactions, and pneumonitis
2. Patient will receive prophylaxis for *Pneumocystis jirovecii* (PJP)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory chronic lymphocytic leukemia (CLL)
2. Relapsed or refractory small lymphocytic lymphoma (SLL)
3. Breast implant-associated anaplastic large cell lymphoma (ALCL)
4. Hepatosplenic T-Cell lymphoma
5. Peripheral T-Cell lymphoma (PTCL)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for serious toxicities including infections, diarrhea or colitis, cutaneous reactions, and pneumonitis
3. Patient will receive prophylaxis for *Pneumocystis jirovecii* (PJP)

Policy Guidelines

Pre - PA Allowance

None

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Prior - Approval Limits

Quantity 168 capsules per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.

Policy History

Date	Action
October 2018	Addition to PA
November 2018	Annual review
March 2019	Annual review
June 2020	Annual review and reference update
March 2021	Annual editorial review
June 2021	Annual review and reference update
March 2022	Annual review and reference update. Per FEP, addition of NCCN off-label indications: gastric MALT lymphoma, nongastric MALT lymphoma, nodal marginal zone lymphoma, splenic marginal zone lymphoma, breast

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June 2022	implant-associated anaplastic large cell lymphoma (ALCL), hepatosplenic T-Cell lymphoma, peripheral T-Cell lymphomas (PTCL) Per PI Update: removed indication for relapsed, refractory follicular lymphoma (FL). Per NCCN no longer recommended uses update, removed the following off-label indications: gastric MALT lymphoma, nongastric MALT lymphoma, nodal marginal zone lymphoma, splenic marginal zone lymphoma
September 2022	Annual review and reference update
December 2022	Annual review and reference update
March 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual editorial review and reference update. Per PI update, changed requirement from “prior therapies” to “prior lines of systemic therapies”, added treatment-related mortality as a boxed warning, added limitations of use

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.