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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	October 12, 2018
Subject:	Copiktra	**Page:**	1 of 5

Last Review Date: March 8, 2024

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 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: (1)

1. Relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies

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 fatal and/or serious infections; diarrhea or colitis; cutaneous reactions; and pneumonitis. Copiktra should be withheld if any of these 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).

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

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

1. Relapsed or refractory chronic lymphocytic leukemia (CLL)
    a. Patient has had at least **TWO** prior therapies
2. Relapsed or refractory small lymphocytic lymphoma (SLL)

a. Patient has had at least **TWO** prior 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

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; December 2021.
2. NCCN Drugs & Biologics Compendium® Duvelisib 2024. National Comprehensive Cancer Network, Inc. Accessed on January 22, 2024.

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 implant-associated anaplastic large cell lymphoma (ALCL), hepatosplenic T-Cell lymphoma, peripheral T-Cell lymphomas (PTCL)
June 2022	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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.