UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1261-8
Program	Prior Authorization/Notification
Medication	Copiktra® (duvelisib)
P&T Approval Date	11/2018, 11/2019, 11/2020, 11/2021,5/2022, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Copiktra (duvelisib) is a dual inhibitor of phosphoinositide 3-kinases (PI3Kδ and PI3Kγ) 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 therapies.[1] The National Cancer Comprehensive Network (NCCN) also recommends the use of Copiktra for the treatment of hepatosplenic T-cell lymphoma after two first-line therapy regimens and as second-line and subsequent therapy for relapsed/refractory breast implant-associated anaplastic large cell lymphoma (ALCL). The NCCN also recommends Copiktra as initial palliative intent therapy or second-line and subsequent therapy for relapsed/refractory for certain peripheral T-cell lymphomas.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Copiktra** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)</u>

1. **<u>Initial Authorization</u>**

   a. **Copiktra** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) History of failure, contraindication, or intolerance to at least **two** prior therapies for CLL/SLL. Examples include, but not limited to, regimens consisting of: Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Calquence (acalabrutinib), Venclexta (venetoclax), etc.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Copiktra** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Copiktra therapy

Authorization will be issued for 12 months.

C. T-cell Lymphomas

1. **Initial Authorization**

a. **Copiktra** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of Hepatosplenic T-cell lymphoma

-AND-

(b) Disease is relapsed or refractory

-AND-

(c) History of failure, contraindication, or intolerance to at least **two** prior systemic therapies

-OR-

(2) **All** of the following:

(a) Diagnosis of Breast implant-associated anaplastic large cell lymphoma

-AND-

(b) Disease is relapsed or refractory

-AND-

(c) Used as second-line and subsequent therapy

-OR-

(3) **Both** of the following:

(a) Diagnosis of Peripheral T-cell lymphoma

-AND-

(b) **One** of the following:

i. Used as initial palliative intent therapy

ii. Used as second-line and subsequent therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Copiktra** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Copiktra therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Copiktra [package insert]. Las Vegas, NV: Secura Bio; July 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed on March 31, 2025.

Program	Prior Authorization/Notification – Copiktra (duvelisib)
Change Control	
11/2018	New program.
11/2019	Annual review. Added coverage for additional B cell lymphomas. Added NCCN recommended regimens criteria. Updated background and references.
11/2020	Annual review. Added additional first line NCCN treatment examples. No change to clinical criteria. Updated references.
11/2021	Annual review with no change to clinical criteria. Updated reference.
5/2022	Annual review. Removed coverage for gastric and nongastric MALT lymphomas, splenic marginal zone lymphoma, and nodal marginal zone lymphoma. Added coverage for T-cell lymphomas. Updated background and references.
5/2023	Annual review. Added state mandate. Updated the background with no changes to clinical criteria. Updated references.
5/2024	Annual review with no change to clinical criteria. Updated reference.
5/2025	Annual review. Updated criteria for peripheral T-cell Lymphoma based on NCCN guidance. Updated references and background.