UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1261-4
Program	Prior Authorization/Notification
Medication	Copiktra® (duvelisib)
P&T Approval Date	11/2018, 11/2019, 11/2020, 11/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

1. Background:

Copiktra® (duvelisib) is a kinase inhibitor indicated for the treatment of relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies. Copiktra is also indicated for the treatment of relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The National Cancer Comprehensive Network (NCCN) also recommends the use of Copiktra for the treatment of gastric and nongastric MALT lymphoma, nodal marginal zone lymphoma, and splenic marginal zone lymphoma after at least two prior therapies.

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. <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. B-cell Lymphomas

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following:

(a) Follicular lymphoma
(b) Gastric MALT lymphoma
(c) Nodal marginal zone lymphoma
(d) Nongastric MALT lymphoma
(e) Splenic marginal zone lymphoma

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) History of failure, contraindication, or intolerance to at least **two** prior

systemic therapies. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Rituxan (rituximab), Revlimid (lenalidomide) 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.

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.

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]. Needham, MA: Verastem, Inc.; July 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 21, 2021.

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.