



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2018 P 1261-1
Program	Prior Authorization/Notification
Medication	Copiktra <sup>®</sup> (duvelisib)
P&T Approval Date	11/2018
Effective Date	2/1/2019; Oxford only: 2/1/2019

**1. Background:**

Copiktra<sup>®</sup> (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.

**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:**

<p><b>A. <u>Patients less than 19 years of age</u></b></p> <p>1. <b>Copiktra</b> will be approved based on the following criterion:</p> <p>a. Member is less than 19 years of age</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p>a. <b>Copiktra</b> will be approved based on <b><u>all</u></b> of the following criteria:</p> <p>(1) Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)</p> <p style="text-align: center;"><b>-AND-</b></p>
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(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), 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. **Follicular lymphoma**

1. **Initial Authorization**

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

(1) Diagnosis of follicular lymphoma

**-AND-**

(2) Disease is relapsed or refractory

**-AND-**

(3) History of failure, contraindication, or intolerance to at least **two** prior systemic therapies for follicular lymphoma. Examples include, but not limited to, regimens consisting of: [Leukeran (chlorambucil), Gazyva (obinutuzumab), Arzerra (ofatumumab), Bendeka (bendamustine), Imbruvica (ibrutinib), Rituxan (rituximab) 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.**

**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.; September 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed September 26, 2018.
3. NCCN Clinical Practice Guideline (NCCN Guideline™). Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v1.2019. Available at [www.nccn.org](http://www.nccn.org). Accessed September 25, 2018.
4. NCCN Clinical Practice Guideline (NCCN Guideline™). B-Cell Lymphomas v4.2018. Available at [www.nccn.org](http://www.nccn.org). Accessed September 25, 2018.

Program	Prior Authorization/Notification – Copiktra (duvelisib)
<b>Change Control</b>	
11/2018	New program.