



## Commercial/Healthcare Exchange PA Criteria

Effective: December 14, 2018

**Prior Authorization:** Copiktra

**Products Affected:** Copiktra (duvelisib) tablet

**Medication Description:**

Copiktra (duvelisib) is a dual phosphoinositide-3 kinases (PI3K) inhibitor, with activity against PI3K- $\delta$  and PI3K- $\gamma$  isoforms which are overexpressed in hematological malignancies. Copiktra targets both the growth and survival of malignant B-cells and the micro-environment that is needed for their support

Copiktra is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least 2 prior therapies and relapsed or refractory follicular lymphoma (FL) who has received at least 2 prior systemic therapies. The relapsed or refractory FL indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Covered Uses:** Treatment of relapsed or refractory Chronic lymphocytic leukemia (CLL), small lymphocytic leukemia (SLL), and Follicular lymphoma (FL) following at least two prior systemic therapies.

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Diagnosis
2. Chart notes documenting previous therapies tried and failed.

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by, or in consultation with, an Oncologist.

**Coverage Duration:**

Initial: 12 months

Continuation: 3 years

**Other Criteria:**

Approve if the patient meets the following criteria (A, B, AND C):

- A. Patient has a documented diagnosis of one of the following:
  - a. Relapsed or refractory Chronic lymphocytic leukemia (CLL); **OR**
  - b. Small lymphocytic leukemia (SLL); **OR**
  - c. Relapsed or refractory Follicular lymphoma (FL); **AND**
- B. Patient has been treated with at least two prior therapies for CLL OR SLL; **OR**
- C. Patient has been treated with at least two prior systemic therapies for FL.

Last Rev. July 1<sup>st</sup>, 2019



Confidential Information

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**References:**

1. Copiktra [package insert]. Needham, MA; Verastem; September 2018.
2. Lymphoma. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/cancer/lymphoma/index.htm>. Accessed October 29, 2018.
3. Follicular lymphoma. Lymphoma Association. Available at: <https://www.lymphomas.org.uk/about-lymphoma/types/non-Hodgkin-lymphoma/follicularlymphoma>. Accessed October 29, 2018.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	12/14/2018
2	Policy Update	Added continuation coverage of 3 years	Coverage Duration	7/1/2019