

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Copiktra Prior Authorization Policy

- Copiktra® (duvelisib capsules – Secura Bio)

**REVIEW DATE:** 06/12/2024

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### OVERVIEW

Copiktra, a phosphatidylinositol 3-kinase (PI3K) inhibitor, is indicated for the treatment of relapsed or refractory **chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)** after at least two prior therapies in adults.<sup>1</sup>

### Guidelines

Copiktra is discussed in guidelines from the National Comprehensive Cancer Network (NCCN).

- **CLL/SLL:** NCCN guidelines (version 3.2024 – March 26, 2024) recommend Copiktra as subsequent therapy for relapsed or refractory disease after prior Bruton tyrosine kinase inhibitor and Venclexta®-(venetoclax tablets) based regimen in patients with or without deletion (del)[17p]/TP53 mutation as “other recommended regimens” (category 2A).
- **T-Cell Lymphoma:** NCCN guidelines (version 04.2024 – May 28, 2024) recommend Copiktra as “preferred” initial palliative intent therapy or second-line or and subsequent therapy for peripheral T-cell lymphoma; as second-line and subsequent therapy for relapsed/refractory disease for breast implant-associated anaplastic large cell lymphoma; and for hepatosplenic T-cell lymphoma as a single agent for refractory disease after two first-line therapy regimens (all category 2A).<sup>3</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Copiktra. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Copiktra is recommended in those who meet one of the following:

#### FDA-Approved Indications

1. **Chronic Lymphocytic Leukemia.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has tried at least one Bruton tyrosine kinase inhibitor; AND  
Note: Examples of a Bruton tyrosine kinase inhibitor includes: Imbruvica (ibrutinib capsules, tablets, and oral solution); Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), or Jaypirca (pirtobrutinib tablets).
  - C) Patient has tried at least one Venclexta-based regimen.

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2. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has tried at least one Bruton tyrosine kinase inhibitor; AND  
Note: Examples of a Bruton tyrosine kinase inhibitor includes: Imbruvica (ibrutinib capsules, tablets, and oral solution); Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib tablets), or Jaypirca (pirtobrutinib tablets).
  - C) Patient has tried at least one Venclexta-based regimen.

#### **Other Uses with Supportive Evidence**

3. **T-Cell Lymphoma.** Approve for 1 year if the patient meets BOTH of the following (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient meets ONE of the following (i or ii):
    - i. Patient meets BOTH of the following (a and b):
      - a) Patient has relapsed or refractory disease; AND
      - b) Patient has breast implant-associated anaplastic large cell lymphoma or hepatosplenic T-cell lymphoma; OR
    - ii. Patient has peripheral T-cell lymphoma.

#### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Copiktra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### **REFERENCES**

1. Copiktra<sup>®</sup> capsules [prescribing information]. Las Vegas, NV: Secura Bio; December 2021.
2. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2024 – March 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 6, 2024
3. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 6, 2024.

