PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Copiktra Prior Authorization Policy
- Copiktra® (duvelisib capsules – Secura Bio)

REVIEW DATE: 06/12/2024

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.[1]

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).[3]

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 ≥ 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.

2. **Small Lymphocytic Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B and C):
   A) Patient is ≥ 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 ≥ 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® 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.