PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/04/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 lines of systemic therapy in adults.[1]

Limitations of Use: Copiktra is not indicated or recommended for the treatment of any patients with CLL or SLL as initial or second-line treatment due to an increased risk of treatment-related mortality.[1]

Guidelines

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

- **CLL/SLL:** NCCN guidelines (version 3.2025 – April 2, 2025) recommend Copiktra as subsequent therapy for relapsed or refractory disease after prior Bruton tyrosine kinase inhibitor and B-cell lymphoma 2 inhibitor-containing regimen in patients with

or without deletion (del)[17p]/TP53 mutation as "other recommended regimens" (category 2A).

- **T-Cell Lymphoma:** NCCN guidelines (version 2.2025 – May 28, 2025) recommend Copiktra as "preferred" initial palliative intent therapy or second-line 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 as a single agent for hepatosplenic T-cell lymphoma 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.

- **Copiktra® (duvelisib capsules - Secura Bio)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 B-cell lymphoma 2 inhibitor.
     Note: Example of a B-cell lymphoma 2 inhibitor includes Venclexta (venetoclax tablets).

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 B-cell lymphoma 2 inhibitor.
     Note: Example of a B-cell lymphoma 2 inhibitor includes Venclexta (venetoclax tablets).

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 COVERED

- **Copiktra® (duvelisib capsules - Secura Bio)**

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as newly published data are available):

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

REFERENCES

1. Copiktra® capsules [prescribing information]. Las Vegas, NV: Secura Bio; July 2024.
2. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2025 – April 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 30, 2025.
3. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 30, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	**Chronic Lymphocytic Leukemia:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen. **Small Lymphocytic Lymphoma:** The requirement that the patient has tried at least two systemic regimens was changed to one systemic regimen. **T-Cell Lymphoma:** The requirement that the patient has relapsed or refractory disease was changed to only apply to patients with breast implant-associated anaplastic large cell lymphoma or hepatosplenic T-cell lymphoma.	06/28/2023
Annual Revision	**Chronic Lymphocytic Leukemia:** Criteria were added which states that the patient has tried at least one Bruton tyrosine kinase inhibitor with a note with examples of a Bruton tyrosine kinase inhibitor AND patient has tried at least one Venclexta-based regimen. The criterion which states that the patient has tried at least one systemic regimen with a note of examples of a systemic regimen were removed. **Small Lymphocytic Lymphoma:** Criteria were added which states that the patient has tried at least one Bruton tyrosine kinase inhibitor with a note with examples of a Bruton tyrosine kinase inhibitor AND patient has tried at least one Venclexta-based regimen. The criterion which states that the patient has tried at	06/12/2024

	least one systemic regimen with a note of examples of a systemic regimen were removed.	
Annual Revision	**Chronic Lymphocytic Leukemia:** The requirement that the patient has tried at least one Venclexta-based regimen was reworded to "Patient has tried at least one B-cell lymphoma 2 inhibitor". A Note of an example of a B-cell lymphoma 2 inhibitor was added. **Small Lymphocytic Lymphoma:** The requirement that the patient has tried at least one Venclexta-based regimen was reworded to "Patient has tried at least one B-cell lymphoma 2 inhibitor". A Note of an example of a B-cell lymphoma 2 inhibitor was added.	06/04/2025