Clinical Policy: Duvelisib (Copiktra)

Reference Number: PA.CP.PHAR.400
Effective Date: 01.19
Last Review Date: 01.19

Revision Log

Description
Duvelisib (Copiktra™) is a kinase inhibitor.

FDA Approved Indication(s)
Copiktra is indicated for:

- Treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies
- Treatment of adult patients with relapsed or refractory follicular lymphoma (FL)* after at least two prior systemic therapies

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**This indication is approved under accelerated approval based on overall response rate (ORR); continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.*

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Copiktra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (must meet all)**:**

1. Diagnosis of relapsed or refractory CLL or SLL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Member has received at least one prior systemic therapy;
   **Prior authorization may be required*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 50 mg (2 capsules) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Follicular Lymphoma (must meet all)**:**

1. Diagnosis of relapsed or refractory FL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 18 years;
4. Member has received at least two prior systemic therapies;
   **Prior authorization may be required*
5. Request meets one of the following (a or b):
   a. Dose does not exceed 50 mg (2 capsules) per day;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 50 mg (2 capsules) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CLL: chronic lymphocytic leukemia	FL: follicular lymphoma
FDA: Food and Drug Administration	SLL: small lymphocytic lymphoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of CLL/SLL first line and subsequent therapies (NCCN)		
chlorambucil ± (ofatumumab or obinutuzumab or rituximab) or any of these agents alone	Varies	Varies
ibrutinib		
High-dose methylprednisolone (HDMP) + rituximab		
bendamustine + CD20 monoclonal antibody or + (rituximab ± ibrutinib or (idelalisib + ibrutinib))		
FCR (fludarabine, cyclophosphamide, rituximab)		
FR (fludarabine, rituximab)		
PCR (pentostatin, cyclophosphamide, rituximab)		
acalabrutinib		
rituximab ± (alemtuzumab, venetoclax, idelalisib or lenalidomide)		
FC (fludarabine, cyclophosphamide) + ofatumumab		
Examples of FL first line and subsequent therapies (NCCN)		
bendamustine + (obinutuzumab or rituximab)	Varies	Varies
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + (obinutuzumab or rituximab)		
RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)		
CVP (cyclophosphamide, vincristine, prednisone) + obinutuzumab		
RCVP (rituximab, cyclophosphamide, vincristine, prednisone)		
rituximab ± (lenalidomide, chlorambucil, or cyclophosphamide)		
ibritumomab tiuxetan, obuinutuzumab, idelalisib, or copanlisib as single agents		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): None reported
- Boxed warning(s): Fatal and serious toxicities: infections, diarrhea or colitis, cutaneous reactions, and pneumonitis

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CLL/SLL, FL	25 mg PO BID with or without food. A cycle consists of 28 days.	50 mg/day

VI. Product Availability

Capsules: 25 mg, 15 mg

VII. References

1. Copiktra Prescribing Information. Needham, MA: Verastem, Inc.; September 2018. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/211155s000lbl.pdf. Accessed September 28, 2018.
2. National Comprehensive Cancer Network. Chronic lymphocytic leukemia/small lymphocytic lymphoma. Version 2.2019. Available at www.nccn.org. Accessed September 28, 2018.
3. National Comprehensive Cancer Network. B-cell lymphomas. Version 5.2018. Available at www.nccn.org. Accessed September 28, 2018.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed September 28, 2018.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01.19	