RXADVANCE
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Clinical Policy Title:	duvelisib
Policy Number:	RxA.360
Drug(s) Applied:	Copiktra®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Duvelisib (Copiktra®) is a kinase inhibitor. It 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. *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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
duvelisib (Copiktra®)	CLL / SLL, FL	25 mg PO BID. A cycle consists of 28 days. Reduce dose to 15 mg twice daily when co-administered with strong CYP3A4 inhibitors.	50 mg/day

Dosage Forms

- Capsules: 25 mg, 15 mg

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age 18 years of age or older;
4. Relapsed/refractory disease after at least one prior therapy (*see Appendix B for examples*);*
   **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*).
**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

B. Follicular and Marginal Zone Lymphomas (must meet all)**:**
1. One of the following diagnoses (a or b):
   a. Follicular Lymphoma;
   b. Marginal zone lymphoma (off-label) (i, ii, or iii):
      i. Splenic marginal zone lymphoma;
      ii. Nodal marginal zone lymphoma;
      iii. Extranodal marginal zone lymphoma (a or b):
         a) Gastric MALT lymphoma;
         b) Nongastric MALT lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age 18 years of age or older;
4. Relapsed/refractory disease after ≥ 2 prior therapies (*see Appendix B for examples*);*
   **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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Copiktra for a covered indication and has received this medication for at least 30 days;
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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CLL: Chronic Lymphocytic Leukemia
FDA: Food and Drug Administration
FL: Follicular Lymphoma
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
CLL/SLL *Examples of first-line, second-line and subsequent therapies:* • FCR (fludarabine, cyclophosphamide, rituximab) • HDMP (high-dose methylprednisolone) + rituximab • Single-agent examples: Imbruvica® (ibrutinib); Venclexta® (venetoclax) ± Gazyva® (obinutuzumab) or rituximab; Campath® (alemtuzumab) ± rituximab; Gazyva; Copiktra® (duvelisib); Calquence® (acalabrutinib); Revlimid® (lenalidomide) ± rituximab; Arzerra® (ofatumumab) ± FC (fludarabine, cyclophosphamide); Leukeran® (chlorambucil) + rituximab	Varies	Varies
Follicular Lymphoma *Examples of first-line, second-line and subsequent therapies:* • bendamustine + Gazyva or rituximab • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) + Gazyva or rituximab • CVP (cyclophosphamide, vincristine, prednisone) + Gazyva or rituximab • Single-agent examples: rituximab; Revlimid ± rituximab	Varies	Varies
Marginal Zone Lymphomas *Examples of first-line, second-line and subsequent therapies:* • bendamustine + rituximab	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
• RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) • RCVP (rituximab, cyclophosphamide, vincristine, prednisone) • Single-agent examples: rituximab; Leukeran ± rituximab; cyclophosphamide ± rituximab; Imbruvica; Revlimid ± rituximab; Copiktra; Aliqopa® (copanlisib)		

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.

APPENDIX D: General Information

- Not applicable

References

1. Copiktra Prescribing Information. Needham, MA: Verastem, Inc.; July 2019. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/211155s000lbl.pdf. Accessed August 02, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed August 02, 2020.
3. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 4.2020. Available at www.nccn.org. Accessed August 02, 2020.
4. National Comprehensive Cancer Network. B-Cell Lymphomas Version 2.2020. Available at www.nccn.org. Accessed August 02, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Initial and Continued Approval Duration: Commercial approval duration was updated from 'length of benefit' to '6 months'. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently	08/02/2020	09/14/2020

Review/Revision History	Review/Revised Date	P&T Approval Date
receiving medication that has been authorized by RxAdvance..." 5. References were updated.		