Clinical Policy Title:	duvelisib
Policy Number:	RxA.360
Drug(s) Applied:	Copiktra®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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 a hematologist;
3. Age ≥ 18 years;
4. Relapsed/refractory disease after at least two prior therapies;
   *Prior authorization may be required.
5. Prescribed as a single agent;
6. Request meets one of the following (a, b or c):*
   a. Dose does not exceed 50 mg per day;
   b. Dose does not exceed 80 mg per day if co-administered with a moderate CYP3A4 inducer;
   c. 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: 12 months
Medicaid: 6 months

B. T-Cell Lymphomas (off-label) (must meet all):

1. Diagnosis is one of the following (a, b or c):
   a. Hepatosplenic T-Cell Lymphoma after 2 first-line therapy regimens;
   b. Breast Implant-Associated ALCL after at least one prior therapy;
   c. Peripheral T-Cell Lymphomas in one of the following settings (i or ii):
      i. Initial palliative intent therapy;
      ii. After at least one prior therapy;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent for relapsed/refractory disease;
5. 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: 12 months

Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is 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, b or c):*
   a. New dose does not exceed 50 mg per day;
   b. Dose does not exceed 80 mg per day if co-administered with a moderate CYP3A4 inducer;
   c. 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: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed April 14, 2023.
2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed April 14, 2023.

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 receiving medication that has been authorized by RxAdvance..." 5. References were updated.	08/02/2020	09/14/2020
Policy was reviewed. 1. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 2. Initial Approval Criteria IA.4 was updated from "Relapsed/refractory disease after at least one prior therapy" to "Relapsed/refractory disease after at least two prior therapies…".	06/02/2021	09/14/2021

Review/Revision History	Review/Revised Date	P&T Approval Date
3. References were reviewed and updated.		
Policy was reviewed. 1. Initial Approval Criteria, I.B: Updated to remove approval criteria for Follicular and Marginal Zone Lymphomas. 2. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, T-Cell Lymphomas (off-label). 3. References were reviewed and updated.	03/17/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to include new prescribing criteria Prescribed as a single agent. 2. Initial Approval Criteria I.A and I.B: Commercial approval duration updated from 6 months to 12 months. 3. Continued therapy approval criteria II.A: Commercial and Medicaid duration updated from 6 months to 12 months. 4. Initial Approval Criteria, I.B.1.a, I.B.1.b and I.B.1.c: Updated diagnostic criteria from Diagnosis is one of the following (a, b or c): a. Hepatosplenic T-Cell Lymphoma; b. Breast Implant-Associated ALCL; c. Peripheral T-Cell Lymphomas to Diagnosis is one of the following (a, b or c): a. Hepatosplenic T-Cell Lymphoma after 2 first-line therapy regimens; b. Breast Implant-Associated ALCL after at least one prior therapy; c. Peripheral T-Cell Lymphomas in one of the following settings (i or ii): i. Initial palliative intent therapy; ii. After at least one prior therapy. 5. Initial Approval Criteria, I.B.3: Updated to include new age criteria Age ≥ 18 years. 6. Continued Therapy Approval, II.A.3.b: Updated to include new dosing criteria Dose does not exceed 80 mg per day if co-administered with a moderate CYP3A4 inducer. 7. References were reviewed and updated.	4/14/2023	7/13/2023
Policy was reviewed.	10/19/2023	10/19/2023