# RAdvance

Clinical Policy Title:	mogamulizumab-kpkc
Policy Number:	RxA.252
Drug(s) Applied:	Poteligeo®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

### Criteria

### I. Initial Approval Criteria

### A. Mycosis Fungoides/Sézary Syndrome (must meet all):

- 1. Diagnosis of MF or SS (relapsed or refractory disease);
- 2. Prescribed by or in consultation with an oncologist or a hematologist;
- 3. Member has received at least one prior systemic therapy;
- 4. Age  $\geq$  18 years;
- 5. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 1 mg/kg on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle;
  - 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 EDA approved or recommended by NCCN

### \*Prescribed regimen must be FDA-approved or recommended by NCCN.

## Approval Duration

**Commercial:** 6 months **Medicaid:** 6 months

### B. Adult T-Cell Leukemia/Lymphoma (off-label) (must meet all):

- 1. Diagnosis of relapsed or refractory adult T-cell leukemia/lymphoma (ATLL);
- 2. Prescribed by or in consultation with an oncologist or a hematologist;
- 3. Age  $\geq$  18 years;
- Trial and failure of first-line therapy;
  - \*Prior authorization may be required.
- Dose is within FDA maximum limit for any FDA-approved indication or 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

### 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 the member has

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Revised 10/2023



met initial approval criteria for covered indication and has received the medication for at least one 28day cycle;

- 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 1 mg/kg on days 1 and 15 of each 28-day cycle;
  - 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: 12 months

#### References

- 1. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2022. Available at: <u>https://www.nccn.org/professionals/physician\_gls/pdf/primary\_cutaneous.pdf</u>. Accessed December 28, 2022.
- 2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 2.2022 Available at: <u>https://www.nccn.org/professionals/physician\_gls/pdf/t-cell.pdf.</u> Accessed December 28, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
<ol> <li>Policy was reviewed:</li> <li>Policy title was updated.</li> <li>Continued Therapy Approval criteria II.A.1 was rephrased.</li> <li>References were updated.</li> </ol>	06/20/2020	09/14/2020
<ol> <li>Policy was reviewed:</li> <li>Initial Approval Criteria I.B.1 was updated to include "relapsed or refractory".</li> <li>Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration.</li> <li>Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance".</li> <li>References were reviewed and updated.</li> </ol>	07/13/2021	09/14/2021
<ul> <li>Policy was reviewed:</li> <li>1. Initial Approval Criteria I.B.5: Updated from used as second line therapy prior to high dose therapy/autologous stem cell rescue (HDT/ASCR); to Used as second line or subsequent therapy in patients with acute or lymphoma subtypes which did not respond to first-line therapy;</li> </ul>	02/04/2022	04/18/2022

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2. References were reviewed and updated.		
<ul> <li>Policy was reviewed:</li> <li>1. Initial Approval Criteria I.B.5: Updated to remove Used as second line or subsequent therapy in patients with acute or lymphoma subtypes which did not respond to first-line therapy.</li> <li>2. References were reviewed and updated.</li> </ul>	12/28/2022	4/13/2023
Policy was reviewed.	10/19/2023	10/19/2023