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 ≥ 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 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 ≥ 18 years;
4. Trial and failure of first-line therapy;
   *Prior authorization may be required.
5. 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

met initial approval criteria for covered indication and has received the medication for at least one 28-day 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: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed December 28, 2022.
2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 2.2022 Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed December 28, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title was updated. 2. Continued Therapy Approval criteria II.A.1 was rephrased. 3. References were updated.	06/20/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.B.1 was updated to include "…relapsed or refractory…". 2. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	07/13/2021	09/14/2021
Policy was reviewed: 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;	02/04/2022	04/18/2022

2. References were reviewed and updated.		
Policy was reviewed: 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. 2. References were reviewed and updated.	12/28/2022	4/13/2023
Policy was reviewed.	10/19/2023	10/19/2023