Clinical Policy Title:	mogamulizumab-kpkc
Policy Number:	RxA.252
Drug(s) Applied:	Poteligeo®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Mogamulizumab-kpkc (Poteligeo®) is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody.

Poteligeo® is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
mogamulizumab-kpkc (Poteligeo®)	MF, SS	1 mg/kg Intravenous infusion over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle until disease progression or unacceptable toxicity	1 mg/kg/dose

Dosage Forms

- Single-dose vial: 20 mg/5 mL (4 mg/mL) solution.

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 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 hematologist;
3. Age ≥ 18 years;
4. Failure of first-line therapy (see Appendix B for examples);
*Prior authorization may be required.
5. Used as second line therapy prior to high dose therapy/autologous stem cell rescue (HDT/ASCR);
6. 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. 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: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
ATLL: adult T-cell leukemia/lymphoma
CCR4: CC chemokine receptor type 4
CTCL: cutaneous T-cell lymphoma
FDA: Food and Drug Administration
MF: mycosis fungoides
NCCN: National Comprehensive Cancer Network
SS: Sézary syndrome
HDT: high dose therapy

ASCR: autologous stem cell rescue
mAb: monoclonal antibody
ADCC: antibody-dependent cellular cytotoxicity

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
ATLL: examples of first-line therapy: • Adectris + CHP (cyclophosphamide, doxorubicin, and prednisone) • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) • CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone) • Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • Hyper-CVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine	Varies	Varies

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Poteligeo® is a humanized monoclonal antibody (mAb) that selectively targets and binds to CCR4-positive malignant T-cells, mediating the process of antibody-dependent cellular cytotoxicity (ADCC). Through this process, it activates immune effector cells (natural killer cells and monocytes) triggering the release of cytotoxic molecules that kill CCR4-positive malignant T-cells.
- Poteligeo® was developed with proprietary Potelligent® technology that enhances ADCC by removing fucose from the mAb's Fc receptor region through a process called defucosylation. Defucosylation increases binding affinity to effector cells, which may increase ADCC activity by up to 100-fold compared with conventionally fucosylated mAbs.

References

1. Poteligeo® Prescribing Information. Bedminster, NJ: Kyowa Kirin, Inc.; August 2018. Available at: https://www.poteligeohcp.com/assets/files/full-prescribing-information.pdf. Accessed July 13, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 13, 2021.

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6. Poteligeo®. MF & SS, MOA. Kyowa Krin, Inc. Bedminster, NJ. Available At: https://www.poteligeohcp.com/poteligeo/mechanism-of-action.html. Accessed July 13, 2021.

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. Appendices updated 4. References were updated	06/20/2020	09/14/2020
Policy was reviewed: 1. Dosing Information was updated from “1 mg/kg Intravenous over at least 60 minutes..” to “1 mg/kg Intravenous infusion over at least 60 minutes..” for better clarity. 2. Dosage Forms was updated from " Single-dose vial: 20 mg/5 mL (4 mg/mL)" to “Single-dose vial: 20 mg/5 mL (4 mg/mL) solution” for better clarity. 3. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 4. Initial Approval Criteria I.B.1 was updated to include “…relapsed or refractory…”. 5. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 6. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is	07/13/2021	09/14/2021

Review/Revision History	Review/Revised Date	P&T Approval Date
currently receiving medication that has been authorized by RxAdvance...". 7. Appendix A was updated to include abbreviations HDT, ASCR, mAb, and ADCC. 8. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 9. Appendix B: Therapeutic Alternatives was updated to remove inactive generic drug name “brentuximab vedotin” and to instead include its comparable Brand name drug “Adectris”. 10. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 11. References were reviewed and updated.		