

Clinical Policy: Mogamulizumab-kpkc (Poteligeo)

Reference Number: ERX.SPA.352

Effective Date: 12.01.19

Last Review Date: 11.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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.

Policy/Criteria

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Poteligeo is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of MF or SS;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. 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: 6 months

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

1. Diagnosis of adult T-cell leukemia/lymphoma (ATLL);
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age \geq 18 years;
4. Failure of first-line therapy (*see Appendix B for examples*);*
**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: 6 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Poteligeo for a covered indication and has received this 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 subsequent 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: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

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

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ATLL: examples of first-line therapy: <ul style="list-style-type: none"> • Brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, and prednisone) • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) • CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone) • Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine 	Varies	Varies

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

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
MF, SS	1 mg/kg IV 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

VI. Product Availability

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

VII. References

1. Poteligeo Prescribing Information. Bedminster, NJ: Kyowa Kirin, Inc.; August 2018. Available at: <https://www.poteligeo.com>. Accessed August 11, 2021.
2. [National Comprehensive Cancer Network Drugs and Biologics Compendium](http://www.nccn.org/professionals/drug_compendium). Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 11, 2021.
3. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August 11, 2021.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed August 11, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.20.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.15.20	11.20
4Q 2021 annual review: no significant changes; modified continuation of care criteria from previously received for at least 30 days to at least one 28-day cycle; references reviewed and updated.	08.11.21	11.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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