

Clinical Policy: Mogamulizumab-kpkc (Poteligeo)

Reference Number: CP.PHAR.139

Effective Date: 09.04.18

Last Review Date: 11.18

Line of Business: Commercial, Medicaid, HIM-Medical Benefit

[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.

It is the policy of health plans affiliated with Centene Corporation[®] 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*).

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to the member's renewal date, whichever is longer

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

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

Approval duration:

Medicaid/HIM – 6 months

Commercial – 6 months or to the member’s renewal date, whichever is longer

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, 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 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*).

Approval duration:

Medicaid/HIM – 12 months

Commercial – 6 months or to the member’s renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

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

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical.

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

3. 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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)	Varies	Varies
CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone)	Varies	Varies
Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)	Varies	Varies
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

Appendix D: General Information

- The NCCN recommends Poteligeo as a primary and subsequent systemic treatment for MF and SS and as a second-line/subsequent therapy for adult T-cell leukemia/lymphoma (category 2A).
- MF and SS are subtypes of cutaneous T-cell lymphoma (CTCL). MF is the most common subtype, accounting for 50-70% of cases, and has primary cutaneous involvement. SS accounts for approximately 3% of CTCL cases and is a leukemic form of CTCL that is characterized by significant blood involvement and lymphadenopathy.
- CCR4 is involved in cell trafficking of lymphocytes to skin and is consistently expressed on the surface of tumor cells in T-cell malignancies such as MF and SS. Of note, patients in the pivotal MAVORIC trial were included regardless of baseline tumor CCR4 expression status.
- Adult T-cell leukemia/lymphoma is caused by the human T-cell lymphotropic virus type 1 (HTLV-1) and is endemic to several regions, including southwest Japan, the Caribbean, and central Africa. It is rare in North America and Europe.

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

Solution for injection in a 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.accessdata.fda.gov/drugsatfda_docs/label/2018/761051s000lbl.pdf. Accessed August 9, 2018.
2. National Comprehensive Cancer Network. T-Cell Lymphomas Version 5.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed August 20, 2018.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 20, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.04.18	11.18

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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