Clinical Policy: Mogamulizumab-kpkc (Poteligeo)

Reference Number: PA.CP.PHAR.139
Effective Date: 10.17.18
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Revision Log

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 PA Health & Wellness® 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. 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: 6 months

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. Failure of a first-line chemotherapy regimen (*see Appendix B for examples*);
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: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 policies – PA.CP.PMN.53 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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