Clinical Policy: Mogamulizumab-kpkc (Poteligeo)

Reference Number: LA.PHAR.139
Effective Date: 09.15.22
Last Review Date: 06.02.23~~08.22~~
Line of Business: Medicaid

Revision Log

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

****Please note: This policy is for medical benefit****

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
~~***Prior authorization is required.***~~ *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 Louisiana Healthcare Connections 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 ≥ 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:
~~**Medicaid**~~ 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 ≥ 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:
~~**Medicaid –**~~ 6 months

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

1. ~~Refer to the off-~~If this drug has recently (within the last 6 months) undergone a label ~~use~~ change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy ~~if~~, refer to LA.PMN.255
2. ~~1.~~If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 ~~for Medicaid~~.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections 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 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:
Medicaid – 12 months

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

~~1.~~ If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255 ~~Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy. Approval duration: Duration of request or 6 months (whichever is less); or~~

1. ~~Refer to the off-label use policy if~~
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized~~): LA~~) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 ~~for Medicaid.~~

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 policyies – LA.PMN.53 for Medicaid, 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 require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ATLL: examples of first-line therapy: • 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~~March 2022. Available at: https://www.poteligeohcp.com. Accessed August ~~11, 2021~~08, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~11, 2021~~08, 2022.
3. National Comprehensive Cancer Network. Primary Cutaneous Lymphomas Version 2.~~2021~~2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed August ~~11, 2021~~8, 2022.
4. National Comprehensive Cancer Network. T-Cell Lymphomas Version ~~1.2021~~2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed August ~~11, 2021~~8, 2022.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9204	Injection, mogamulizumab-kpkc, 1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	09.22	09.15.22
no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications. Added verbiage this policy is for medical benefit only.	06.02.23	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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