Poteligeo® (mogamulizumab-kpkc)
(Intravenous)

Document Number: IC-0378

Last Review Date: 04/01/2026
Date of Origin: 09/05/2018
Dates Reviewed: 09/2018, 10/2019, 10/2020, 10/2021, 10/2022, 10/2023, 10/2024, 4/2025, 4/2026

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
  - Adult T-Cell Leukemia/Lymphoma combination therapy with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), followed by single agent therapy: Prior authorization validity may be provided for up to a maximum of eight 14 day or 21 day treatment cycles.
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
  - Adult T-Cell Leukemia/Lymphoma combination therapy with CHOP, followed by single agent therapy: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- All Indications: 120 billable units days 1, 8, 15, and 22 of the first 28-day cycle, then 120 billable units every 14 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Cutaneous Lymphoma (Mycosis Fungoides/Sezary Syndrome) † ‡ Φ [1,2,4]

- Used as single agent systemic therapy**; AND**
  - Used as subsequent therapy; **OR**
  - Used as primary treatment *(excluding use in members with stage IA mycosis fungoides)* **‡**

Adult T-Cell Leukemia/Lymphoma ‡ [2,3]

- Used as single agent systemic therapy; **AND**
  - Used as subsequent therapy in members with chronic high risk, acute, or lymphoma subtypes which did not respond to first-line therapy; **OR**
- Used in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP), followed by single agent therapy, in members with no intention to proceed to transplant; **AND**

- Used as first-line therapy for chronic high risk, acute, or lymphoma subtypes; **OR**
- Used as continued treatment in responders to first-line therapy for acute or lymphoma subtypes; **OR**
- Used as additional therapy for nonresponders to first-line therapy for smoldering symptomatic or chronic low risk subtypes; **OR**
- Used as additional therapy for nonresponders to first-line therapy with zidovudine and interferon for chronic high risk subtype; **OR**
- Used as additional therapy (if not previously used) for nonresponders to first-line therapy for acute subtype

† FDA Approved Indication(s); **‡** Compendia Recommended Indications(s); **Φ** Orphan Drug

IV. Renewal Criteria [1]

Prior authorization validity can be renewed based on the following criteria:

- Member continues to meet the universal and indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: dermatologic toxicity (e.g., Stevens-Johnson syndrome [SJS] and toxic epidermal necrolysis [TEN], etc.), severe infusion reactions, severe infections, autoimmune complications, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

V. Dosage/Administration [1,6,7]

Indication	Dose
Cutaneous Lymphoma (Mycosis Fungoides/Sezary Syndrome)	Administer 1 mg/kg intravenously on days 1, 8, 15 and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity.
Adult T-Cell Leukemia/Lymphoma	<u>Single Agent:</u> Administer 1 mg/kg intravenously on days 1, 8, 15 and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity. <u>Combination with CHOP, followed by single agent therapy:</u> Administer 1 mg/kg intravenously every 14 to 21 days in combination with CHOP for six (6) 14-day or 21-day cycles, followed by two (2) 14-day or 21-day cycles of monotherapy.

VI. Billing Code/Availability Information

HCPCS Code:

- J9204 – Injection, mogamulizumab-kpkc, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Poteligeo 20 mg/5 mL single-dose vial: 42747-0761-xx

VII. References

1. Poteligeo [package insert]. Princeton, NJ; Kyowa Kirin, Inc.; February 2026. Accessed February 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for mogamulizumab-kpkc. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2026.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) T-Cell Lymphomas Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2026.
4. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) Cutaneous Lymphomas Version 2.2026. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2026.
5. Kim YH, Bagot M, Eradat HA, et al. Phase 3 study of anti-CCR4 monoclonal antibody mogalizumab versus vorinostat in relapsed or refractory cutaneous T-cell lymphoma (CTCL). Journal of Clinical Oncology 2014 32:15_suppl, TPS8623-TPS8623.
6. Phillips AA, Fields PA, Hermine O, et al. Mogamulizumab versus investigator's choice of chemotherapy regimen in relapsed/refractory adult T-cell leukemia-lymphoma. Haematologica 2019;104:993-1003.
7. Yoshimitsu M, Choi I, Kusumoto S, et al. A phase 2 Trial of CHOP with anti-CCR4 antibody mogamulizumab for older patients with adult T-cell leukemia/lymphoma. Blood 2025:146;1440-1449. doi:10.1182/blood.2024027902.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen

ICD-10	ICD-10 Description
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC