

Poteligeo[®] (mogamulizumab-kpkc) (Intravenous)

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Document Number: EOCCO-0478

Last Review Date: 10/30/2023

Date of Origin: 07/01/2019

Dates Reviewed: 07/2019, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023

I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Poteligeo 20 mg single-dose vial: 24 vials per the first 28 days, then 12 vials each subsequent 28 days

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

- All Indications: 120 billable units (120 mg) days 1,8,15 and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28-day cycle

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

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

Universal Criteria ¹

- Used as single agent systemic therapy; **AND**

Mycosis Fungoides (MF)/Sezary Syndrome (SS) † ‡ Φ ^{1,2,4,5}

- Used as subsequent therapy for relapsed or refractory disease; **AND**
- Patient has stage IB-IV disease; **AND**
- Patient does not have large-cell transformation (LCT)

Adult T-Cell Leukemia/Lymphoma ‡ ²

- Used as subsequent therapy in patients with acute or lymphoma subtypes which did not respond to first-line therapy

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

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

IV. Renewal Criteria ¹

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal and indication-specific relevant criteria identified in section III; **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 allogenic hematopoietic stem cell transplantation (HSCT), etc.

V. Dosage/Administration ^{1,6}

Indication	Dose
All Indications	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.

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 (STANDARD)

1. Poteligeo [package insert]. Bedminster, NJ; Kyowa Kirin, Inc.; March 2023. Accessed October 2023.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for mogamulizumab-kpkc. National Comprehensive Cancer Network, 2023. 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 October 2023.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium[®]) T-Cell Lymphomas Version 1.2023. National Comprehensive Cancer Network, 2023. 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 October 2023.
4. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium[®]) Primary Cutaneous Lymphomas Version 1.2023. National Comprehensive Cancer Network, 2023. 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 October 2023.
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 P, Hermine O, et al. A prospective, multicenter, randomized study of anti-CCR4 monoclonal antibody mogamulizumab (moga) vs investigator's choice (IC) in the treatment of patients (pts) with relapsed/refractory (R/R) adult T-cell leukemia-lymphoma (ATL). *J Clin Oncol.* 2016;34(15_suppl):7501-7501.

VIII. References (ENHANCED)

- 1e. Prince HM, Kim YH, Horwitz SM, et al. Brentuximab vedotin or physician's choice in CD30-positive cutaneous T-cell lymphoma (ALCANZA): an international, open-label, randomised, phase 3, multicentre trial. *Lancet.* 2017 Aug 5;390(10094):555-566.
- 2e. Duvic M, Tetzlaff MT, Gangar P, Clos AL, Sui D, Talpur R. Results of a Phase II Trial of Brentuximab Vedotin for CD30+ Cutaneous T-Cell Lymphoma and Lymphomatoid Papulosis. *J Clin Oncol.* 2015;33(32):3759–3765.
- 3e. Kim YH, Tavallae M, Sundram U, et al. Phase II Investigator-Initiated Study of Brentuximab Vedotin in Mycosis Fungoides and Sézary Syndrome With Variable CD30 Expression Level: A Multi-Institution Collaborative Project. *J Clin Oncol.* 2015;33(32):3750–3758.

- 4e. Duvic M, Hymes K, Heald P, et al. Bexarotene is effective and safe for treatment of refractory advanced-stage cutaneous T-cell lymphoma: multinational phase II-III trial results. *J Clin Oncol*. 2001 May 1;19(9):2456-71.
- 5e. Olsen EA, Kim YH, Kuzel TM, et al. Phase IIb multicenter trial of vorinostat in patients with persistent, progressive, or treatment refractory cutaneous T-cell lymphoma. *J Clin Oncol*. 2007 Jul 20;25(21):3109-15.
- 6e. Whittaker SJ, Demierre MF, Kim EJ, et al. Final results from a multicenter, international, pivotal study of romidepsin in refractory cutaneous T-cell lymphoma. *J Clin Oncol*. 2010 Oct 10;28(29):4485-91.
- 7e. Kaplan EH, Rosen ST, Norris DB, et al. Phase II study of recombinant human interferon gamma for treatment of cutaneous T-cell lymphoma. *J Natl Cancer Inst*. 1990 Feb 7;82(3):208-12.
- 8e. Zackheim HS, Kashani-Sabet M, McMillan A. Low-dose methotrexate to treat mycosis fungoides: a retrospective study in 69 patients. *J Am Acad Dermatol*. 2003 Nov;49(5):873-8.
- 9e. Ishida T, Joh T, Uike N, et al. Defucosylated anti-CCR4 monoclonal antibody (KW-0761) for relapsed adult T-cell leukemia-lymphoma: a multicenter phase II study. *J Clin Oncol*. 2012 Mar 10;30(8):837-42.
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- 11e. Ishida T, Fujiwara H, Nosaka K, et al. Multicenter Phase II Study of Lenalidomide in Relapsed or Recurrent Adult T-Cell Leukemia/Lymphoma: ATLL-002. *J Clin Oncol*. 2016; 34(34):4086-4093.
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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

ICD-10	ICD-10 Description
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
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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered 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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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