

Poteligeo® (mogamulizumab-kpkc) (Intravenous)

Document Number: IC-0378

Last Review Date: 10/01/2020

Date of Origin: 09/05/2018

Dates Reviewed: 09/2018, 10/2019, 10/2020

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 therapy; **AND**

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

- Patient has relapsed or refractory disease; **AND**
 - Patient has received at least one previous systemic therapy † (*note: topical and/or photochemotherapy cannot be considered systemic therapies*); **OR**
- Used as primary treatment as systemic therapy (*excluding use for stage IA mycosis fungoides with B1 blood involvement*) ‡

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

† 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 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, fatal and life-threatening infections, autoimmune complications, etc.

V. Dosage/Administration

Indication	Dose
All Indications	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

1. Poteligeo [package insert]. Bedminster, NJ; Kyowa Kirin, Inc.; August 2018. Accessed September 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for mogamulizumab-kpkc. National Comprehensive Cancer Network, 2020. 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 September 2020.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium[®]) T-cell Lymphomas Version 1.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN

POTELIGEO[®] (mogamulizumab-kpkc) Prior Auth Criteria

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4. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) Primary Cutaneous Lymphomas Version 2.2020. National Comprehensive Cancer Network, 2020. 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 September 2020.
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. Palmetto GBA, LLC. Local Coverage Article: Billing and Coding: Chemotherapy (A56141). Centers for Medicare & Medicaid Services, Inc. Updated on 05/26/2020 with effective date of 04/30/2020. Accessed September 2020.

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

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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)

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) and 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: <http://www.cms.gov/medicare-coverage-database/search/advanced-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):

Jurisdiction(s): J & M	NCD/LCD/LCA Document (s): A56141
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=A56141&bc=gAAAAAAAAAAAA	

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, 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