Poteligeo® (mogamulizumab-kpkc)
(Intravenous)

-E-

Document Number: IC-0478

Last Review Date: 10/26/2020
Date of Origin: 07/01/2019
Dates Reviewed: 07/2019, 11/2019, 11/2020

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 [1,2,5]

- 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*); **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); Φ 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 (STANDARD)

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 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.
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.

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, Tavallaee 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.

10e. Ishida T, Utsunomiya A, Jo T, et al. Mogamulizumab for relapsed adult T-cell leukemia-lymphoma: Updated follow-up analysis of phase I and II studies. Cancer Sci. 2017;108(10):2022–2029.

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12e. 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.

13e. Sharma K, Janik JE, O'Mahony D, et al. Phase II Study of Alemtuzumab (CAMPATH-1) in Patients with HTLV-1-Associated Adult T-cell Leukemia/lymphoma. Clin Cancer Res. 2016;23(1):35–42.

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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
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

ICD-10	ICD-10 Description
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) 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=gAAAAAAAAAAA	

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.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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

Appendix 3 – CLINICAL LITERATURE REVIEW

OS = overall survival; PFS = progression-free survival; ORR = objective response rate; CR = complete response; PR = partial response; DoR = duration of response; TTP = time to progression; FFS = failure-free survival; EFS = event-free survival; PFR = progression free rate; LCT = large cell transformation

Mycosis Fungoides (MF)/Sezary Syndrome (SS)

Relapsed or refractory disease							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Mogamulizumab	2A preferred (primary or subsequent treatment of stage IA-III MF and stage IV Sezary syndrome)	Yes (relapsed or refractory MF/SS only)	Phase 3 (MAVORIC), randomized, open-label, multicenter	Vorinostat	PFS	After at least one prior systemic therapy	• Mogamulizumab significantly prolonged progression-free survival compared with vorinostat. Patients with large cell transformation were excluded from this study.
Brentuximab vedotin	2A preferred (primary therapy and for relapsed or refractory disease)	Yes (CD30+ MF relapsed or refractory disease only)	Phase 3 (ALCANZA), international, open-label, randomized, multicenter	Physician's Choice (methotrexate or bexarotene)	ORR ≥ 4 months	After at least one prior systemic therapy	• Significant improvement in objective response lasting at least 4 months was seen with brentuximab vedotin versus physician's choice of methotrexate or bexarotene
Brentuximab vedotin	2A preferred (primary therapy and for relapsed or refractory disease)	Yes (CD30+ MF relapsed or refractory disease only)	Phase 2, open-label	N/A	----------	After at least one prior therapy	• Brentuximab vedotin is both active and well tolerated in cutaneous T-cell lymphoma with an ORR of 73% and CR of 35%.

Brentuximab vedotin	2A preferred (primary therapy and for relapsed or refractory disease)	Yes (CD30+ MF relapsed or refractory disease only)	Phase 2, investigator-initiated, multi-institution	N/A	ORR	After at least one prior therapy	• Brentuximab vedotin demonstrated significant clinical activity with an ORR of 70% in treatment-refractory or advanced MF or SS with a wide range of CD30 expression levels
Bexarotene	2A preferred	Yes	Phase 2/3	N/A	ORR	Refractory to conventional therapy	• Bexarotene is effective for the treatment of advanced, refractory MF/SS with an ORR of 45-55%.
Vorinostat	2A preferred	Yes (after at least two prior systemic therapies)	Phase 2b, multi-center	N/A	ORR	After least two prior systemic therapies at least one of which included bexarotene unless intolerable	• Oral vorinostat was effective in treatment refractory MF/SS
Romidepsin	2A preferred	Yes (after at least one prior systemic therapy)	Phase 2b (GPI-04-0001), open-label	N/A	ORR	After one or more prior systemic therapies	• Romidepsin demonstrated an ORR of 34% in patients with refractory CTCL
Primary treatment							
Regimen	**NCCN Category**	**FDA Approved**	**Trial Design**	**Comparator**	**Primary End-Point**	**Line of Therapy**	**Conclusion**
Mogamulizumab	2A preferred	No	No evidence to support use.				
Interferon gamma	2A preferred	No	Phase 2	N/A		Previously treated with	• Interferon gamma demonstrated efficacy with a PR of 31%

						topical and/or systemic therapy	
Methotrexate	2A preferred	No	Retrospective study	N/A	-----	----------	• Low-dose methotrexate resulted in an ORR of 33%.