

Corporate Medical Policy

Mogamulizumab-kpkc (Poteligeo[®])

File Name:	mogamulizumab_poteligeo
Origination:	1/2019
Last CAP Review:	3/2020
Next CAP Review:	3/2021
Last Review:	3/2020

Description of Procedure or Service

Mogamulizumab-kpkc (Poteligeo[®]) is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody that is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.

Mycosis fungoides (MF) and Sézary syndrome (SS) are subtypes of cutaneous T-cell lymphomas (CTCL), which are rare non-Hodgkin lymphomas characterized by skin involvement. MF is the most common form of CTCL and presents on the skin as lesions, plaques, and generalized erythroderma. MF progresses slowly and can have extracutaneous involvement of the lymph nodes, blood, and less commonly other organs in advanced disease. SS is rarer, yet more aggressive, and is characterized by erythroderma, lymphadenopathy, and blood involvement with cancerous T-cells. MFSS together represent two-thirds of all CTCL. The median overall survival of patients with advanced stages of MFSS is roughly 5 years. There is no curative treatment for CTCL other than allogeneic hematopoietic stem cell transplantation. Treatment resistant or advanced disease requires systemic treatment, and patients often experience disease progression or resistance to standard systemic therapies.

Mogamulizumab-kpkc (Poteligeo) was approved by the U.S. Food and Drug Administration (FDA) in August 2018 for the treatment of relapsed or refractory MFSS. It works by binding to CCR4 receptors found on T-cell malignancies, which are involved with lymphocyte trafficking to various organs.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for mogamulizumab-kpkc (Poteligeo[®]) when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Mogamulizumab-kpkc (Poteligeo®)

When Mogamulizumab-kpkc (Poteligeo) is covered

Initial Therapy

Mogamulizumab-kpkc (Poteligeo) is considered medically necessary for the treatment of adult patients (≥ 18 years old) with mycosis fungoides or Sézary syndrome after at least one prior systemic therapy when the following criteria are met:

- The patient has histologically confirmed diagnosis of mycosis fungoides or Sézary syndrome; **and**
- The patient has relapsed or refractory disease

Initial authorization: 12 months

Continuation Therapy

Continuation of treatment with mogamulizumab-kpkc (Poteligeo) beyond 12 months after initiation of therapy, and every 12 months thereafter, is considered medically necessary for the treatment of mycosis fungoides or Sézary syndrome when the following criteria are met:

- The patient has been receiving mogamulizumab-kpkc treatment previously; **and**
- The patient has demonstrated a durable clinical benefit while receiving mogamulizumab-kpkc treatment, with partial or complete response or stable disease

Use of mogamulizumab-kpkc (Poteligeo) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, (see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Mogamulizumab-kpkc (Poteligeo) is not covered

Mogamulizumab-kpkc (Poteligeo) is considered **investigational** and therefore not covered when the above criteria are not met.

Mogamulizumab-kpkc (Poteligeo) is considered investigational when used for:

1. Non-cancer indications; **OR**
2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under “When Mogamulizumab-kpkc (Poteligeo) is covered.”

Policy Guidelines

Mogamulizumab-kpkc (Poteligeo[®])

The recommended dose of Poteligeo is 1 mg/kg given as an intravenous (IV) infusion over at least 60 minutes. Poteligeo is administered 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 occurs. Premedication with diphenhydramine and acetaminophen should be given prior to the first Poteligeo infusion.

According to the manufacturer's safety information for Poteligeo, the most common adverse reactions (incidence $\geq 20\%$) include rash, infusion related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection.

The efficacy of mogamulizumab-kpkc (Poteligeo) was evaluated by the MAVORIC study (NCT01728805). This phase 3, open-label, multicenter, randomized controlled trial assessed 372 adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS). Patients included in the trial were at least 18 years of age and had stage IB-IVB, histologically confirmed relapsed or refractory MF or SS. Eligible patients had also failed (for progression or toxicity) at least one previous systemic therapy, had an ECOG (Eastern Cooperative Oncology Group) score of 1 or less, and had adequate hematological, hepatic, and renal function. Patients were included in the trial regardless of tumor CCR4 expression status, and the median number of prior systemic therapies was 3. Patients were randomized in a 1:1 ratio to receive either mogamulizumab 1 mg/kg intravenously weekly for the first 28-day cycle then on days 1 and 15 of subsequent cycles (n=186; 56% with MF, 44% with SS), or vorinostat 400 mg daily (n=186; 53% with MF, 47% with SS). Treatment continued until disease progression, drug intolerance, or unacceptable toxicity, and patients treated with vorinostat who experienced disease progression or unacceptable toxicity were allowed to cross over to mogamulizumab treatment. The median duration of follow-up was 17 months. The primary endpoint was investigator-assessed progression-free survival (PFS), which was significantly prolonged in the mogamulizumab group compared to the vorinostat group (median 7.7 months [95% CI 5.7-10.3] in the mogamulizumab group vs 3.1 months [2.9-4.1] in the vorinostat group; hazard ratio 0.53, 95% CI 0.41-0.69; stratified log-rank $p < 0.0001$). Other efficacy endpoints included overall response rate (ORR), duration of response, proportion of patients with an overall response in the crossover portion of the trial, quality of life, and safety. Results demonstrated that mogamulizumab significantly prolonged PFS compared to vorinostat.

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: J9204

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Mogamulizumab-kpkc (Poteligeo[®])

Scientific Background and Reference Sources

Kyowa Kirin, Inc. Poteligeo (mogamulizumab-kpkc) injection for intravenous use. Highlights of prescribing information. August 2018. Available at: https://www.poteligeohcp.com/?gclid=EAIaIQobChMIx-3E7ZDD3wIVAtbACh2YOgZcEAAYASAAEgKbKfD_BwE. Accessed December 2018.

U.S. Food and Drug Administration. FDA approves treatment for two rare types of non-Hodgkin lymphoma. Available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm616176.htm>. Accessed December 2018.

Kim YH, Bagot M, Pinter-Brown L, et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomized, controlled phase 3 trial. *Lancet Oncol*. 2018; 19(9):1192-204.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. T-Cell Lymphomas, version 2.2019. Revised December 17, 2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed December 2018.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Primary Cutaneous Lymphomas, version 2.2019. Revised December 17, 2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed December 2018.

Medical Director review 1/2019

Specialty Matched Consultant Advisory Panel – 3/2019

Specialty Matched Consultant Advisory Panel – 3/2020

Policy Implementation/Update Information

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| 1/29/19 | New policy developed. Poteligeo is considered medically necessary for the treatment of adult patients (≥ 18 years old) with mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. Added HCPCS code C9038, J3490, J3590, and J9999 to Billing/Coding section. References added. Medical Director review 1/2019. (krc) |
| 4/16/19 | Specialty Matched Consultant Advisory Panel review 3/20/2019. No change to policy statement. (krc) |
| 10/1/19 | Added HCPCS code J9204 to Billing/Coding section and deleted codes C9038, J3490, J3590, and J9999 effective 10/1/19. (krc) |
| 4/14/20 | Specialty Matched Consultant Advisory Panel review 3/18/2020. No change to policy statement. (krc) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

