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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Poteligeo[®] (mogamulizumab-kpkc intravenous injection)

HCPCS: J9204

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. Prescribed by or in consultation with an oncologist or dermatologist
 - b. FDA approved age
 - c. FDA approved indication
 - d. Trial and failure of at least one prior systemic therapy
 - e. Eastern Cooperative Oncology Group (ECOG) performance score of ≤ 1
 - f. Must be used as monotherapy
 - g. Have not received prior treatment with any CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody
 - h. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list
- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limits: Based on FDA approved dosing
 - b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
 - c. Renewal Criteria: Continuation of therapy until disease progression or unacceptable toxicity

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Poteligeo is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.
- Efficacy was established in the MAVORIC study, a phase III, open-label, randomized trial of 372 patients with adult patients with MF or SS after at least one prior systemic therapy. Patients were included if they had a ECOG performance score less than or equal to 1. Patients were randomized to receive either Poteligeo monotherapy at a dose of 1 mg/kg on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle. or oral vorinostat capsules at a dose of 400 mg daily. Treatment was continued until unacceptable toxicity or disease progression. Compared with the vorinostat group, the median progression-free survival (PFS) was significantly longer for patients in the Poteligeo group: 7.7 months (95% confidence interval [CI]: 5.7, 10.3) for the Poteligeo group vs. 3.1 months (95% CI: 2.9, 4.1) for the vorinostat group (p-value < 0.0001). The proportion of patients who achieved an overall response was also significantly higher in the Poteligeo group compared with the vorinostat group (28% vs. 5%, respectively; p-value < 0.001).
- Poteligeo has not been studied for use in combination with other therapies to treat MF or SS and should be used as monotherapy only.
- There are no studies to support use of Poteligeo following failure of its use. National Comprehensive Cancer Network 2026 primary cutaneous lymphoma guidelines also do not recommend use of Poteligeo or any other CCR4-directed monoclonal antibodies following a previous failure.

References:

1. Poteligeo [prescribing information]. Bedminister, NJ: Kyowa Kirin; January 2025.
2. National Comprehensive Cancer Network. Cutaneous lymphomas (Version 2.2026). 2026 Feb 13. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed on February 24, 2026.
3. Duvic M, Pinter-Brown LC, Foss FM, et al. Phase 1/2 study of mogamulizumab, a defucosylated anti-CCR4 antibody, in previously treated patients with cutaneous T-cell lymphoma. Blood. 2015; 125: 1883–89.
4. Kim YH, Bagot M, Pinter-brown L, et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. Lancet Oncol. 2018; 19 (9): 1192 - 1204.

Policy History		
#	Date	Change Description
2.1	Effective Date: 04/16/2026	Updated to include the trial and failure of preferred products statement
2.0	Effective Date: 04/10/2025	Annual review – no changes to criteria at this time
1.9	Effective Date: 04/11/2024	Annual review – no changes to criteria at this time
1.8	Effective Date: 04/06/2023	Updated approval length to allow for no less than a 60 day approval duration
1.7	Effective Date: 10/06/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time
1.6	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

1.5	Effective Date: 12/01/2020	UM medical management system update for BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	Yes											
BCNA	Yes											
1.4	Effective Date: 10/08/2020	Updated to only allow for 6 months on renewal										
1.3	Effective Date: 01/01/2020	UM medical management system update for BCNA and MAPPO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	No											
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MAPPO	Yes											
BCNA	Yes											
1.2	Effective Date: 11/07/2019	Annual Review of Medical Policy										
1.1	Effective Date: 08/01/2019	UM medical management system update for BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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1.0	Effective Date: 11/01/2018	New Policy <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.*