UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Poteligeo Utilization Management Medical Policy
- Poteligeo® (mogamulizumab-kpkc intravenous infusion – Kyowa Kirin)

REVIEW DATE: 09/10/2025

OVERVIEW
Poteligeo, a CC chemokine receptor 4 (CCR4)-directed monoclonal antibody, is indicated for the treatment of relapsed or refractory **mycosis fungoides** or **Sézary syndrome** in adults after at least one prior systemic therapy.[1]

GUIDELINES
Poteligeo is addressed in the National Comprehensive Cancer Network (NCCN) guidelines:
- **Primary Cutaneous Lymphomas:** Guidelines (version 3.2025 – June 10, 2025) recommend Poteligeo for primary treatment and for treatment of relapsed/refractory mycosis fungoides/Sezary syndrome.[2,3]
- **T-Cell Lymphomas:** Guidelines (version 2.2025 – May 28, 2025) recommend Poteligeo as a single agent for the second-line or subsequent treatment of relapsed/refractory adult T-cell leukemia/lymphoma; chronic high-risk, acute or lymphoma subtypes.[3,4]

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Poteligeo. Coverage is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Request for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Due to the specialized skills required for evaluation and diagnosis of patients treated with Poteligeo, as well as the monitoring required for adverse events and long-term efficacy, approval requires Poteligeo to be prescribed by, or in consultation with, a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Poteligeo is recommended in those who meet one of the following criteria:

FDA-Approved Indication

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1. **Mycosis Fungoides/Sézary Syndrome.** Approve for 1 year if patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with an oncologist or dermatologist.

   Dosing. Approve 1 mg/kg by intravenous infusion no more frequently than 4 times in each 28-day cycle.

Other Uses With Supportive Evidence

2. Adult T-cell Leukemia/Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has chronic high risk, acute, or lymphoma subtypes; AND
- **C)** The medication is used as second-line or subsequent therapy; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 1 mg/kg by intravenous infusion no more frequently than 4 times in each 28-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Poteligeo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Poteligeo® intravenous infusion [prescribing information]. Bedminster, NJ: Kyowa Kirin; January 2025.
2. NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 3.2025 – June 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 26, 2025.
3. NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 26, 2025. Search terms: mogamulizumab-kpkc.
4. NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 26, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/06/2023
Annual Revision	No criteria changes.	09/04/2024
Annual Revision	**Mycosis Fungoides/Sézary Syndrome:** The requirement that the patient is ≥ 18 years of age was added. **Adult T-Cell Leukemia/Lymphoma**: The requirements that patient is ≥ 18 years of age and patient has chronic high risk, acute, or lymphoma subtypes were added. Patient has relapsed or refractory disease was changed to "the medication is used as second-line or subsequent therapy".	09/10/2025