POLICY: Poteligeo® (mogamulizumab-kpkc injection for intravenous use – Kyowa Kirin, Inc.)

APPROVAL DATE: 09/04/2019

OVERVIEW

Poteligeo is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on Primary Cutaneous Lymphomas (version 2.2019 – December 17, 2018) recommend Poteligeo for primary treatment and for treatment of relapsed/refractory mycosis fungoides/Sezary syndrome.[2,3]

The NCCN guidelines on T-Cell Lymphomas (version 2.2019 – December 17, 2018) recommend Poteligeo as a single agent for the treatment of relapsed/refractory adult T-cell leukemia/lymphoma, acute or lymphoma subtypes.[3,4]

Other Uses With Supportive Evidence

In a Phase II, open-label trial, 71 patients with adult T-cell leukemia/lymphoma were randomized (2:1) to mogamulizumab (n = 47) or investigators choice of treatment (n =24).[5] Patients in the mogamulizumab arm received 1.0 mg/kg once weekly during the first 28-day cycle and then biweekly in subsequent cycles. The primary endpoint was the confirmed overall response rate (cORR) defined as a response that was confirmed 8 weeks after the initial response. The cORR in the mogamulizumab arm was 11% (95% confidence interval [CI]: 4%, 23%) compared with 0% in the investigator choice arm (95% CI: 0%, 14%).

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.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Poteligeo is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Mycosis Fungoides/Sézary Syndrome.** Approve for 1 year if Poteligeo is prescribed by or in consultation with an oncologist or dermatologist.

   Dosing. Approve the following dosing regimen: Administer up to 1 mg/kg by intravenous infusion no more frequently than 4 times in each 28-day cycle.[1]

Uses With Supportive Evidence

2. **Adult T-cell Leukemia/Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A and B):
   A) The patient has relapsed or refractory disease; AND
   B) Poteligeo is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen: Administer up to 1 mg/kg by intravenous infusion no more frequently than 4 times in each 28-day cycle.[1,5]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Poteligeo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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® injection [prescribing information]. Bedminster, NJ: Kyowa Kirin, Inc.; August 2018.
2. NCCN Primary Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019 – December 17, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 22, 2019.
3. NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 22, 2019. Search terms: mogamulizumab-kpkc.
4. NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 2.2019 – December 17, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 22, 2019.
5. Phillips AA, Fields PA, Hermine O, et al. Mogamulizumab versus investigator's choice of chemotherapy regimen in relapsed/refractory adult T-cell leukemia/lymphoma. *Haematologica*. 2019;104:993-1003.

HISTORY

Type of Revision	Summary of Changes	Approval Date
New Policy	--	09/05/2018
Selected revision	Updated NCCN guidelines version to 5.2018. Added Adult T-cell leukemia/lymphoma (ATLL) as an approvable indication in the "Other uses with supporting evidence" section (included in the NCCN guidelines).	10/17/2018
Annual	Combined mycosis fungoides and Sezary syndrome criteria into one indication and removed relapsed/refractory criteria and removed at least one prior systemic therapy criteria. Revised Adult T-cell leukemia/lymphoma criteria by removing CCR4 positive ATLL and removing dermatologist. Removed Waste Management section from the policy.	9/04/2019