SPECIALTY GUIDELINE MANAGEMENT

POTELIGEO (mogamulizumab-kpkc)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. <u>FDA-Approved Indications</u>

Poteligeo is 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.

B. Compendial Uses

- 1. Mycosis fungoides (MF) or Sézary syndrome (SS)
- 2. Adult T-cell leukemia/lymphoma (ATLL)

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Mycosis fungoides (MF) or Sézary syndrome (SS) Authorization of 12 months may be granted for treatment of mycosis fungoides (MF) or Sézary syndrome (SS).

B. Adult T-cell leukemia/lymphoma (ATLL)

Authorization of 12 months may be granted for treatment of ATLL when used as a single-agent subsequent therapy for chronic high risk, acute or lymphoma subtypes.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

- 1. Poteligeo [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; March 2022.
- 2. The NCCN Drugs & Biologics Compendium[®] © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 4, 2024.

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