Reference number(s)
4474-A

STANDARD MEDICARE PART B 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. FDA-Approved Indication
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) as primary treatment
2. Adult T-cell leukemia/lymphoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

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
Authorization of 12 months may be granted for treatment of adult T-cell leukemia/lymphoma as a single agent when used as second line or subsequent therapy for acute or lymphoma subtypes.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Poteligeo
B. Poteligeo is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
1. No evidence of unacceptable toxicity while on the current regimen AND

2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Poteligeo.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Primary cutaneous lymphomas
4. NCCN Guideline: T-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Poteligeo are covered in addition to the following:

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

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Poteligeo to treat mycosis fungoides/Sezary syndrome and adult T-cell leukemia/lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VI. REFERENCES

1. Poteligeo [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; March 2022.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 3, 2023.