Reference number(s)
4474-A

Standard Medicare Part B Management Poteligeo

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Poteligeo	mogamulizumab-kpkc

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.

FDA-approved Indications[1]

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.

Compendial Uses[2]

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

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

Coverage Criteria

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Mycosis fungoides (MF) or Sézary syndrome (SS)[1,2]

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

Adult T-cell leukemia/lymphoma[2]

Authorization of 12 months may be granted for treatment of ATLL when used in one of the following ways:

- As a single agent when used as subsequent therapy for chronic high risk, acute, or lymphoma subtypes.
- In combination with CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone) if no intention to proceed to transplant.

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:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the Coverage Criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen

Summary of Evidence

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

- The prescribing information for Poteligeo.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Primary cutaneous lymphomas
- 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:

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

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).

References

1. Poteligeo [package insert]. Princeton, NJ: Kyowa Kirin, Inc.; January 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 15, 2025.

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