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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2023
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	August 24, 2018
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**Last Review Date:** March 10, 2023

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## Poteligeo

### Description

Poteligeo (mogamulizumab-kpkc)

### Background

Poteligeo (mogamulizumab-kpkc) is a defucosylated, humanized IgG1 kappa monoclonal antibody that binds to CCR4, a G protein-coupled receptor for CC chemokines that is involved in the trafficking of lymphocytes to various organs. Poteligeo binding targets a cell for antibody-dependent cellular cytotoxicity (ADCC) resulting in depletion of the target cells. CCR4 is expressed on the surface of some T-cell malignancies (1).

### Regulatory Status

FDA-approved indications: Poteligeo is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy (1).

Poteligeo may cause fatal and life-threatening skin adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN). Monitor patients for rash throughout the treatment course. Management of dermatologic toxicity includes topical corticosteroids and interruption or permanent cessation of Poteligeo. Discontinue Poteligeo permanently for SJS or TEN or for any life-threatening (Grade 4) reaction. For possible SJS or TEN, interrupt Poteligeo and do not restart unless SJS or TEN is ruled out and the cutaneous reaction has resolved to Grade 1 or less (1).

Fatal and life-threatening infusion reactions can occur with Poteligeo. Most reactions occur during or shortly after the first infusion. Consider premedication (such as diphenhydramine and

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acetaminophen) for the first infusion of Poteligeo in all patients. Monitor patients closely for signs and symptoms of infusion reactions and interrupt the infusion for any grade reaction and treat promptly (1).

Fatal and life-threatening infections and immune-mediated complications can also occur with Poteligeo. Patients should be monitored for signs and symptoms of infection and treat promptly. Interrupt or permanently discontinue Poteligeo as appropriate for suspected immune-mediated adverse reactions. Consider the benefit/risk of Poteligeo in patients with a history of autoimmune disease (1).

The safety and effectiveness of Poteligeo in pediatric patients have not been established (1).

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Poteligeo may be considered **medically necessary** in patients 18 years of age and older with relapsed or refractory mycosis fungoides or Sézary syndrome and if the conditions indicated below are met.

Poteligeo may be considered **investigational** in patients less than 18 years of age and for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age and older

### Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory mycosis fungoides
2. Sézary syndrome

**AND ALL** of the following:

- a. Patient has received prior systemic therapy
- b. **NOT** to be used in combination with Targretin (bexarotene)

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## Prior – Approval *Renewal* Requirements

**Age** 18 years of age and older

### Diagnoses

Patient must have **ONE** of the following:

1. Relapsed or refractory mycosis fungoides
2. Sézary syndrome

**AND NONE** of the following:

- a. Disease progression or unacceptable toxicity
- b. Used in combination with Targretin (bexarotene)

### Policy Guidelines

## Pre - PA Allowance

None

## Prior - Approval Limits

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Poteligeo (mogamulizumab-kpkc) is a defucosylated, humanized IgG1 kappa monoclonal antibody that binds to CCR4, a G protein-coupled receptor for CC chemokines that is involved in the trafficking of lymphocytes to various organs. Poteligeo binding targets a cell for antibody-dependent cellular cytotoxicity (ADCC) resulting in depletion of the target cells. CCR4 is expressed on the surface of some T-cell malignancies. The safety and effectiveness of Poteligeo in pediatric patients have not been established (1).

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Poteligeo while maintaining optimal therapeutic outcomes.

**References**

1. Potelegio [package insert]. Bedminster, NJ: Kyowa Kirin, Inc.; March 2022.
2. NCCN Drugs & Biologics Compendium® Mogamulizumab-kpkc 2023. National Comprehensive Cancer Network, Inc. Accessed on January 23, 2023.

**Policy History**

Date	Action
August 2018	Addition to PA
November 2018	Annual review
June 2019	Annual review
June 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 10, 2023 and is effective on April 1, 2023.