Medical Policy:

Poteligeo® (mogamulizumab-kpkc) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.120	February 25, 2025	January 1, 2019

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Poteligeo (mogamulizumab-kpkc): is a defucosylated, humanized IgG1 kappa monoclonal antibody that binds to CC chemokine receptor type 4 (CCR4), a G protein-coupled receptor for CC chemokines that is involved in the trafficking of lymphocytes to various organs. CCR4 is expressed on the surface of T-cell malignancies, including some types of cutaneous T-cell lymphoma (CTCL). CCR4 and its chemokine ligands are overexpressed in CTCL skin lesions at all stages of disease.

Poteligeo (mogamulizumab-kpkc) is FDA approved for the treatment of adult patients with relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy.

Length of Authorization

Initial coverage will be provided for 6 months. Renewal coverage provided for 12 months.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 1mg/kg x 4 infusions for first 28-day cycle
- 1mg/kg x 2 infusions for subsequent cycle

(120 billable units (120 mg) days 1,8,15 and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28- day cycle)

Guideline

I. INITIAL APPROVAL CRITERIA

Poteligeo *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. Patient must have a diagnosis of **relapsed or refractory mycosis fungoides or Sézary syndrome**; **AND**
2. Patient must be ≥ 18 years old; **AND**
3. Patient must have tried and failed ≥ 1 systemic therapy; **AND**
4. Poteligeo will be used as a single agent therapy.

Limitations/Exclusions

Poteligeo is not considered medically necessary when any of the following selection are met:

1. Poteligeo (mogamulizumab-kpkc) is being used after disease progression with the same regimen.
2. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

1. Patient continues to meet above initial criteria; **AND**
2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
3. Patient has not experienced unacceptable toxicities (e.g. history of Stevens-Johnson syndrome, toxic epidermal necrolysis, life-threatening infusion reaction, and autoimmune complications with this medication).

Dosage/Administration

Indication	Dose
All Indications	1 mg/kg intravenously on days 1, 8, 15 and 22 of the first 28-day cycle, then on days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity.

Applicable Procedure Codes

Code	Description
J9204	Injection, mogamulizumab-kpkc, 1 mg

Applicable NDCs

Code	Description
42747-0761-01	Poteligeo 20mg/5ml single-dose vial

ICD-10 Diagnoses

Code	Description
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.10	Sézary disease, unspecified site
C84.11	Sézary disease, lymph nodes of head, face, and neck
C84.12	Sézary disease, intrathoracic lymph nodes
C84.13	Sézary disease, intra-abdominal lymph nodes
C84.14	Sézary disease, lymph nodes of axilla and upper limb
C84.15	Sézary disease, lymph nodes of inguinal region and lower limb
C84.16	Sézary disease, intrapelvic lymph nodes
C84.17	Sézary disease, spleen
C84.18	Sézary disease, lymph nodes of multiple sites
C84.19	Sézary disease, extranodal and solid organ sites

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/25/2025	Annual Review: Removed C91.5, C91.52. renewal criteria: reworded: "Patient has not experienced disease progression or stabilization of disease; AND" as: "Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND" for clarity
EmblemHealth & ConnectiCare	1/16/2024	Annual Review: No Criteria changes
EmblemHealth & ConnectiCare	5/19/2023	Annual Review: Initial criteria Mycosis Fungiodes/Sezary Syndrome: Removed: "Patient must not have undergone prior allogeneic hematopoietic stem cell transplant (HSCT) or autologous HSCT within the last 90 days; AND Patient is free of active autoimmune disease or active infections; AND Patient does not have evidence of CNS metastases, If female, patient must not be pregnant; verification of pregnancy status should be performed prior to starting therapy; AND If female, patient must be using contraception during therapy and for 3 months after cessation of therapy"
EmblemHealth & ConnectiCare	09/26/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	7/7/2021	Termed C Code

EmblemHealth & ConnectiCare	8/15/2019	Added New Code J9204, effective 10/1/19.
EmblemHealth & ConnectiCare	1/1/2019	New Policy

References

1. Poteligeo [package insert] Kyowa Kirin Inc., Bedminster, NJ, 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.