



Poteligeo® (Mogamulizumab-kpkc)

Last Review Date: September 23, 2019

Number: MG.MM.PH.120

Medical Guideline Disclaimer

Property of EmblemHealth. All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. 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. 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 Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated, GHI HMO Select, ConnectiCare, Inc., ConnectiCare Insurance Company, Inc. ConnectiCare Benefits, Inc., and ConnectiCare of Massachusetts, Inc. related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

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

Max Units (per dose and over time) [Medical Benefit]:

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

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:*

- Patient must have a diagnosis of relapsed or refractory mycosis fungoides or Sézary syndrome; **AND**

- Patient must be ≥ 18 years old; **AND**
- 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; **AND**
- Patient must have tried and failed ≥ 1 systemic therapy; **AND**
- 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; **AND**
- 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:

- Poteligeo (mogamulizumab-kpkc) is being used after disease progression with the same regimen.
- 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

- Patient continues to meet above initial criteria; **AND**
- Patient has not experienced disease progression or stabilization of disease; **AND**
- 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

C9038	Injection, mogamulizumab-kpkc, 1 mg
J9204	Effective 10/1/19, Injection, mogamulizumab-kpkc, 1 mg

Applicable NDCs

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

Applicable Diagnosis Codes

ICD-10	ICD-10 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
C91.50	Adult T-cell lymphoma/leukemia (HTLV-1-associated) not having achieved remission
C91.52	Adult T-cell lymphoma/leukemia (HTLV-1-associated) in relapse

Revision History

8/15/2019	Added New Code J9204, effective 10/1/19.
-----------	--

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.