**Poteligeo® (Mogamulizumab-kpkc)**

**Last Review Date:** September 23, 2019  
**Number:** MG.MM.PH.120

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**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-kpc) 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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>All Indications</td>
<td>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.</td>
</tr>
</tbody>
</table>

Applicable Procedure Codes

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

Applicable NDCs

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

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tbody>
<tr>
<td>C84.00</td>
<td>Mycosis fungoides, unspecified site</td>
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</tbody>
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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