Clinical Policy: Mogamulizumab-kpkc (Poteligeo)
Reference Number: CP.PHAR.139
Effective Date: 09.04.18
Last Review Date: 11.18
Line of Business: Commercial, Medicaid, HIM-Medical Benefit

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Mogamulizumab-kpkc (Poteligeo®) is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody.

FDA Approved Indication(s)
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.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Poteligeo is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Mycosis Fungoides/Sézary Syndrome (must meet all):
   1. Diagnosis of MF or SS;
   2. Prescribed by or in consultation with an oncologist or hematologist;
   3. Age ≥ 18 years;
   4. Request meets one of the following (a or b):
      a. Dose does not exceed 1 mg/kg on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle;
      b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

   Approval duration:
   Medicaid/HIM – 6 months
   Commercial – 6 months or to the member’s renewal date, whichever is longer

B. Adult T-Cell Leukemia/Lymphoma (off-label) (must meet all):
   1. Diagnosis of adult T-cell leukemia/lymphoma;
   2. Prescribed by or in consultation with an oncologist or hematologist;
   3. Age ≥ 18 years;
   4. Failure of a first-line chemotherapy regimen (see Appendix B for examples);
   5. Request meets one of the following (a or b):
      a. Dose does not exceed 1 mg/kg on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**
- Medicaid/HIM – 6 months
- **Commercial** – 6 months or to the member’s renewal date, whichever is longer

### C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical.

### II. Continued Therapy

#### A. All Indications in Section I (must meet all):
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Poteligeo for a covered indication and has received this medication for at least one 28-day cycle;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 1 mg/kg on days 1 and 15 of each 28-day cycle;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**
- Medicaid/HIM – 12 months
- **Commercial** – 6 months or to the member’s renewal date, whichever is longer

#### B. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 6 months (whichever is less); or**
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical.

### III. Diagnoses/Indications for which coverage is NOT authorized:
3. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid and HIM-Medical or evidence of coverage documents.

### IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

- CCR4: CC chemokine receptor type 4
- CTCL: cutaneous T-cell lymphoma
- FDA: Food and Drug Administration
- MF: mycosis fungoides
Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
- The NCCN recommends Poteligeo as a primary and subsequent systemic treatment for MF and SS and as a second-line/subsequent therapy for adult T-cell leukemia/lymphoma (category 2A).
- MF and SS are subtypes of cutaneous T-cell lymphoma (CTCL). MF is the most common subtype, accounting for 50-70% of cases, and has primary cutaneous involvement. SS accounts for approximately 3% of CTCL cases and is a leukemic form of CTCL that is characterized by significant blood involvement and lymphadenopathy.
- CCR4 is involved in cell trafficking of lymphocytes to skin and is consistently expressed on the surface of tumor cells in T-cell malignancies such as MF and SS. Of note, patients in the pivotal MAJORIC trial were included regardless of baseline tumor CCR4 expression status.
- Adult T-cell leukemia/lymphoma is caused by the human T-cell lymphotrophic virus type 1 (HTLV-1) and is endemic to several regions, including southwest Japan, the Caribbean, and central Africa. It is rare in North America and Europe.

V. Dosage and Administration
<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>MF, SS</td>
<td>1 mg/kg IV over at least 60 minutes on days 1, 8, 15, and 22 of the first 28-day cycle and on days 1 and 15 of each subsequent cycle until disease progression or unacceptable toxicity</td>
<td>1 mg/kg/dose</td>
</tr>
</tbody>
</table>
VI. Product Availability
Solution for injection in a single-dose vial: 20 mg/5 mL (4 mg/mL)

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Date</th>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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