Poteligeo (mogamulizmuab-kpkc)

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Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Poteligeo (mogamulizmuab) when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Poteligeo (mogamulizmuab) may be considered medically necessary when all of the following criteria are met:

FDA-Approved Indications

1. Mycosis Fungoides.  Approve for 1 year if the patient meets ALL of the following (A, B and C):
   A) The patient has relapsed or refractory mycosis fungoides; AND
   B) The patient has received at least one prior systemic therapy (e.g., extracorporeal photopheresis, oral retinoid [bexarotene capsules {Targretin®, generics}, tretinoin capsules, isotretinoin capsules {Amnesteem®, Claravis™, generics}, acitretin capsules {Soriatane®, generics}], interferons [Intron-A®/Pegasys® {interferon-alpha injection}, Actimmune® {interferon-gamma injection}], HDAC inhibitors [Zolinza® {vorinostat capsules}, Istodax® {romidepsin injection}], methotrexate, Adcetris® [brentuximab vedotin injection], cyclophosphamide tablets or injection, or Folotyn® [pralatrexate injection]); AND
   C) Poteligeo is prescribed by, or in consultation with, an oncologist or a dermatologist.

   Poteligeo is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides after at least one prior systemic therapy.¹

2. Sézary Syndrome.  Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) The patient has relapsed or refractory Sézary Syndrome; AND
   B) The patient has received at least one prior systemic therapy (e.g., extracorporeal photopheresis, oral retinoid [bexarotene capsules {Targretin®, generics}, tretinoin capsules, isotretinoin capsules
Poteligeo is indicated for the treatment of adult patients with relapsed or refractory Sézary Syndrome after at least one prior systemic therapy.\(^1\)

Other Uses With Supportive Evidence

3. Adult T-cell Leukemia/Lymphoma (ATLL). Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) The patient has relapsed or refractory CCR4-positive ATLL; AND
   B) The patient has received at least one course of chemotherapy; AND
   C) Poteligeo is prescribed by, or in consultation with, an oncologist or a dermatologist.

The NCCN guidelines (version 5.2018) note chemotherapy as initial therapy for ATLL: CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone), dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, and doxorubicin), and hyperCVAD (cyclophosphamide vincristine, doxorubicin, and dexamethasone) alternating with high-dose methotrexate and cytarabine. Second-line therapies include single agents (Adcetris\(^\circledR\) [brentuximab vedotin for injection] for CD30-expressing cases, Revlimid\(^\circledR\) [lenalidomide capsules], and Poteligeo [category 2A designation; off-label use]) and combination agents (e.g., interferon and zidovudine, DHAP [dexamethasone, cisplatin, cytarabine], ESHAP [etoposide, methylprednisolone, cytarabine, cisplatin], GemOx [gemcitabine, oxaliplatin]). The NCCN notes that with Poteligeo, there is a high risk of developing graft-versus-host disease (GVHD), nonrelapse mortality, and overall mortality in patients proceeding to allogeneic hematopoietic cell transplant (HCT) within 50 days of Poteligeo therapy. Therefore, Poteligeo should be used with caution in patients with ATLL who are eligible for or proceeding directly to allogeneic HCT.

The efficacy of Poteligeo was evaluated in two studies involving patients with relapsed or refractory CCR4-positive ATLL (in Japan and outside of Japan).\(^3\)\(^-\)\(^6\) Twenty-eight patients were in the multicenter phase II study in Japan and the overall response rate was 50%; median progression-free survival was 5 months and overall survival was 14 months.\(^3\)\(^-\)\(^5\) Seventy-one patients were in the prospective randomized study conducted outside of Japan. Patients were randomized to receive either Poteligeo or an investigator choice regimen (GemOx [gemcitabine, oxaliplatin], DHAP, or Folotyn\(^\circledR\) [pralatrexate injection]).\(^3\)\(^,\)\(^6\) The overall response rates as assessed by the investigator and independent review were higher for
patients treated with Poteligeo (34% and 23%, respectively) compared with those treated with the investigator choice regimen (0% and 8%, respectively).

When Policy Topic is not covered
Poteligeo (mogamulizmuab) is considered not medically necessary when the above criteria is not met and investigational for all other uses.

Considerations
Poteligeo (mogamulizmuab) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service
Poteligeo is indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. Poteligeo is a recombinant humanized monoclonal antibody that targets CC chemokine receptor 4 (CCR4)-expressing cells. CCR4 is highly expressed on malignant T cells in mycosis fungoides skin lesions and on circulating malignant T cells in patients with Sézary syndrome. Non-clinical in vitro studies show that Poteligeo-CCR4 cell binding targets a cell for antibody-dependent cellular cytotoxicity (ADCC), which results in depletion of the target cells.

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on T-cell lymphomas (version 5.2018) provide treatment recommendations for the different types of T-cell lymphomas. Initial treatment options for patients with mycosis fungoides or Sézary syndrome consist of skin-directed therapies, alone or in combination with other skin-directed therapies, including local radiation. Multiple systemic therapies are recommended for treatment of patients with mycosis fungoides or Sézary syndrome refractory or unresponsive to skin-directed therapies and for patients with more aggressive or advanced disease. NCCN categorizes systemic therapies as Category A, B, or C. Examples of drugs in each category are as follows: Category A: electrocorporeal photopheresis (ECP), interferons (Intron-A®/Pegasys® [interferon-alpha injection], Actimmune® [interferon-gamma injection]), systemic retinoids (bexarotene capsules [Targretin®, generics], tretinoin capsules, isotretinoin [Absorica®, Amnesteem®, Claravis™, Myorisan™, Zenatane™, generics], acitretin capsules [Soriatane®, generics]), HDAC inhibitors (Zolinza® [vorinostat capsules], Istodax® [romidepsin injection]), Poteligeo, low-dose methotrexate (≤ 100 mg once a week), or Adcetris® [brentuximab vedotin injection]; Category B or C: gemcitabine injection [Gemzar®, generics], liposomal doxorubicin injection [Doxil®, generics], Leukeran® [chlorambucil tablets], cyclophosphamide tablets or injection, and
Velcade® [bortezomib injection]). NCCN also recommends use of combination therapies (most commonly, phototherapy plus either interferon or systemic retinoid or ECP plus either interferon or systemic retinoid or both). Participation in a clinical trial is recommended for all patients with refractory or progressive disease.

**Rationale**
Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Poteligeo (mogamulizmuab) while maintaining optimal therapeutic outcomes.

**References**

**Billing Coding/Physician Documentation Information**

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<th>Code</th>
<th>Description</th>
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<tbody>
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<td>J9999</td>
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**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

<table>
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<th>Date</th>
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<tbody>
<tr>
<td>01/2019</td>
<td>New policy titled Poteligeo (mogamulizmuab)</td>
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