



Missouri Care

*'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona
OneCare (Care1st Health Plan Arizona, Inc.)*

Staywell of Florida

Children's Medical Services Health Plan (CMS Health Plan)

*WellCare (Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska,
New Jersey, New York, South Carolina, Tennessee, Texas)*

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Mycosis fungoides and Sézary syndrome are diseases in which lymphocytes become malignant and affect the skin. With mycosis fungoides, T-cell lymphocytes become cancerous and affect the skin and in Sézary syndrome, cancerous T-cell lymphocytes affect the skin as well as the blood. Both diseases are types of cutaneous T-cell lymphoma and are the two most common types of cutaneous T-cell lymphoma. Cutaneous T-cell lymphomas are distinguished from other T-cell lymphomas that involve the skin, such as anaplastic large cell lymphoma, peripheral T-cell lymphoma, adult T-cell leukemia/lymphoma, or subcutaneous panniculitic T-cell lymphoma.^{1,2}

A common sign of mycosis fungoides is a red rash on the skin which may go through stages. The first stage is the premycotic phase where the patient will develop a scaly, red rash in areas of the body that usually are not exposed to the sun. This rash does not cause symptoms and may last for months or years and is difficult to diagnose as mycosis fungoides. Next, the rash will go into the patch phase where the skin becomes thin, reddened, and has an eczema-like appearance. The plaque phase is when small papules or hardened lesions appear on the skin. Finally, the tumor phase is when tumors form on the skin. These tumors may become ulcerous and the skin may get infected. In Sézary syndrome, skin all over the body is reddened, itchy, peeling, and painful. There may also be patches, plaques, or tumors on the skin. Symptoms of the diseases may present for long periods, 2 to 10 years in some cases. Because cutaneous eruptions can get better and worse it may take a while before the patient gets a

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biopsy confirmation.^{1,2}

To diagnose mycosis fungoides or Sézary syndrome patients may have the following tests and procedures:^{1,2}

- Physical exam and history
- Complete blood count with differential
- Peripheral blood smear
- Skin biopsy
- Immunophenotyping
- T-cell receptor (TCR) gene rearrangement test
- Flow cytometry

Mycosis fungoides and Sézary syndrome are treatable with topical therapy, systemic therapy, or both, and can be difficult to cure. Treatment is often focused on relieving symptoms and improving patient quality of life. When a patient is diagnosed, prognosis and treatment options depend on the stage of cancer and presence of lymphadenopathy and involvement of peripheral blood, type of lesion and the patient's age and gender.^{1,2}

Poteligeo[®] (mogamulizumab-kpkc) injection is a CC chemokine receptor type 4 (CCR4)-directed monoclonal antibody indicated for the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. It was approved by the FDA in 2018. Dosing is 1 mg/kg as an intravenous infusion 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. The most common adverse reactions (reported in ≥20% of patients) were rash, infusion related reactions, fatigue, diarrhea, musculoskeletal pain, and upper respiratory tract infection.³

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets
- Medicaid – Florida (CMS Health Plan - CHIP)
- Medicare – All Markets

Exclusions

Poteligeo[®] is **not considered medically necessary and not a covered benefit** when any of the following apply:

- Member has prior intolerance or toxicity to mogamulizumab; **OR**,

Coverage

Poteligeo[®] is **considered medically necessary and a covered benefit** for treatment of relapsed or refractory mycosis fungoides (MF) or Sezary syndrome (SS)

- Member is age 18 years or older; **AND**,
- Member has a histologically confirmed diagnosis of MF or SS; **AND**,
- Member has stage IB to IVB disease; **AND**
- Member has tried and failed (progression of disease or toxicity) at least one prior systemic therapy (methotrexate, bexarotene, vorinostat, romidepsin, brentuximab vedotin, alemtuzumab, interferon, pralatrexate, conventional chemotherapy); **AND**,
- Dose is 1 mg/kg 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; **AND**,
- Approval duration will be 3 months.

Reauthorization:

- Reauthorization will be based on documentation of clinical improvement or maintenance (as evidenced by):

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- Lack of evidence of disease progression
- No evidence of drug toxicity or drug intolerance.

CODING

Covered CPT Codes

- 96413** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- 96415** Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
- 96416** Chemotherapy administration, intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump
- 96417** Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)
- 96422** Chemotherapy administration, intra-arterial; infusion technique, up to 1 hour
- 96423** Chemotherapy administration, intra-arterial; infusion technique, each additional hour (List separately in addition to code for primary procedure)
- 96425** Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump

Covered HCPCS Codes – No Applicable Codes.

Covered ICD-10 Codes

- C84.00-84.09** Mycosis Fungoides
- C91.50-C91.52** Adult T-cell lymphoma/leukemia (HTLV-1 associated)

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/ state law s.

REFERENCES

1. Mycosis fungoides (including Sézary syndrome) treatment (PDQ®) – Patient Version. National Cancer Institute web site <https://www.cancer.gov/types/lymphoma/patient/mycosis-fungoides-treatment-pdq#section/48>. Published September 7, 2017. Accessed October 22, 2018.
2. Mycosis fungoides (including Sézary syndrome) treatment (PDQ®) – health professional version. National Cancer Institute web site <https://www.cancer.gov/types/lymphoma/hp/mycosis-fungoides-treatment-pdq>. Published July 5, 2018. Accessed October 22, 2018.
3. Highlights of prescribing information - Poteligeo®. Kyowa Kirin, Inc. 2018. Found at <https://www.poteligeohcp.com/Content/files/prescribing-information.pdf>.
4. Kim, Y.H., Bagot, B., Pinter-Brown, L., et al. Mogamulizumab versus vorinostat in previously treated cutaneous T-cell lymphoma (MAVORIC): an international, open-label, randomised, controlled phase 3 trial. *The Lancet*, Volume 19. Published September 2018.
5. Olsen EA, Whittaker S, Kim YH, et al. Clinical end points and response criteria in mycosis fungoides and Sezary syndrome: a consensus statement of the International Society for Cutaneous Lymphomas, the United States Cutaneous Lymphoma Consortium, and the Cutaneous Lymphoma Task Force of the European Organization for Research and Treatment of Cancer. *J Clin Oncol*. 2011;29(18):2598–2607.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
11/1/2018	• Approved by MPC. New.