POLICY NUMBER UM_1344	SUBJECT Poteligeo™ (mogamulizumab-kpkc)		DEPT/PROGRAM UM	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/21/18, 09/11/19	APPROVAL DATE September 11, 2019	EFFECTIVE DATE September 11, 2019	COMMITTEE APPROVAL DATES (latest version listed last) 09/21/18, 09/11/19	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Oncology	

I. PURPOSE

To define and describe the accepted indications for Poteligeo (mogamulizumab-kpkc) usage in the treatment of cancer.

II. DEFINITIONS

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.

Poteligeo (mogamulizumab-kpkc) is available as an injection: 20 mg/5 mL (4 mg/mL) solution in a single-dose vial.

III. POLICY

New Century Health is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century Health may be deemed as not approvable and therefore not reimbursable. Treatment request outside the approved FDA manufacturer labeling or CMS approved compendia must follow CMS Medicare Benefit Policy Manual Chapter 15. If references are not produced, delays may occur to the processing of such request.

Inclusion Criteria: Poteligeo (mogamulizumab-kpkc) may be considered medically necessary when any of the following selection criteria are met:

1. **T-Cell Lymphomas**
    a. Poteligeo (mogamulizumab-kpkc) is being for **ONE** of the following:
        i. Mycosis Fungoides/Sezary Syndrome
            A. As primary treatment **OR**
            B. For relapsed/refractory disease after at least one prior systemic therapy
        ii. T-Cell Leukemia/Lymphoma
            A. As second-line therapy, with intention to proceed to high-dose therapy/allogeneic stem cell rescue **OR**
            B. As subsequent therapy to HDT/ASCR as a single agent for non-responders to first-line therapy for acute or lymphoma subtypes.

Exclusion Criteria: Poteligeo (mogamulizumab-kpkc) is not considered medically necessary when any of the following selection criteria are met:

1. Poteligeo (mogamulizumab-kpkc) is being used after disease progression with the same regimen.
2. Member had prior treatment with Vorinostat.
3. Member has a known active infection or autoimmune disease.
4. Dosing exceeds single dose limit of Poteligeo (mogamulizumab-kpkc) 1 mg/kg.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. PROCEDURE

Requests for Poteligeo (mogamulizumab-kpkc) shall be reviewed for appropriateness per FDA approved product labeling, the National Comprehensive Cancer Network (NCCN) and American Society of Clinical Oncology (ASCO) clinical guidelines, or CMS approved compendia.

1. **Dosage and Administration:** 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. Premedication give diphenhydramine and acetaminophen for the first infusion; if an infusion reaction occurs, give premedication (e.g., diphenhydramine and acetaminophen) for subsequent infusions.
2. **Dosage Adjustments:** Dosage adjustments are not required for renal or hepatic impairment.
3. **Monitoring:**
    a. Rash (mild; Grade 1): Consider topical corticosteroid treatment.
    b. Rash (moderate or severe; Grade 2 or 3): Interrupt therapy and administer at least 2 weeks of topical corticosteroids. May resume if rash improves to Grade 1 or less.
    c. Suspected Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN): Stop therapy and do not resume unless SJS or TEN has been excluded and the cutaneous reaction has resolved to Grade 1 or less; permanently discontinue for any SJS or TEN.
    d. Rash (life-threatening; Grade 4 or any SJS or TEN): Permanently discontinue.
    e. Infusion reaction (mild to severe reactions; Grades 1 to 3): Temporarily interrupt infusion and treat symptomatically. Following resolution, reduce the infusion rate by at least 50% when restarting. Discontinue infusion if reaction recurs and is unmanageable.
    f. Infusion reaction (life-threatening reaction; Grade 4): Permanently discontinue therapy.

V. APPROVAL AUTHORITY

1. Review – UM Department
2. Final Approval – UM Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Poteligeo PI prescribing information. Kyowa Kirin, Inc. Bedminster, NJ 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.

4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.