

Drug Policy:

Poteligeo™ (mogamulizumab-kpkc)

POLICY NUMBER UM ONC_1344	SUBJECT Poteligeo™ (mogamulizumab-kpkc)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 09/21/18, 09/11/19, 12/11/19, 05/13/20, 10/14/20	APPROVAL DATE October 14, 2020	EFFECTIVE DATE October 30, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 09/21/18, 09/11/19, 12/11/19, 05/13/20, 10/14/20
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee	
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Poteligeo (mogamulizumab-kpkc) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines](#) shall follow [NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies [AND](#)
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision [AND](#)
5. When available, generic alternatives are preferred over brand-name drugs.

B. Mycosis Fungoides/Sezary Syndrome

1. Poteligeo (mogamulizumab-kpkc) will be used as a single agent for relapsed or refractory mycosis fungoides/Sezary syndrome [AND](#)
2. The member has received and experienced disease progression on [ALL](#) of the following:
 - a. Istodax (romedepsin)
 - b. Folutyn (pralatrexate)
 - c. Targretin (bexaratene)
 - d. Zolinza (vorinostat)
 - e. PUVA therapy (psoralen and ultraviolet A therapy).

III. EXCLUSION CRITERIA

- A. Disease progression while receiving Poteligeo (mogamulizumab-kpkc).
- B. Concurrent use with other systemic therapies (may be used with skin directed therapy or radiation therapy).
- C. Dosing exceeds single dose limit of Poteligeo (mogamulizumab-kpkc) 1 mg/kg.
- D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Poteligeo PI prescribing information. Kyowa Kirin, Inc. Bedminster, NJ 2020.
- B. Clinical Pharmacology Elsevier Gold Standard. 2020.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

- E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.