

# Mogamulizumab-kpkc (POTELIGEO®)

## Criteria for Use

### January 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRANet](#) site for further information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive mogamulizumab-kpkc:

- Care not provided by a VA or VA Community Care hematology/oncology provider
- Evidence of large cell transformation (LCT)
- Evidence of central nervous system (CNS) metastasis
- History of allogeneic or autologous hematopoietic stem cell transplant (HSCT) within past 90 days
- Plan to undergo allogeneic HSCT within the next 6 months
- Chronic or unresolved infection
- Active autoimmune disease (e.g. Graves' disease, SLE, RA, Crohn's, psoriasis)
- ANC < 1500 cells/mm<sup>3</sup>, platelets < 100,000 cells/mm<sup>3</sup> (if marrow involvement, then ANC <1000 and platelets < 75,000)
- Severe hepatic impairment (Child-Pugh Class C), as drug has not been evaluated in this population
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

## Inclusion Criteria

All of the following must be fulfilled in order to meet criteria:

- Diagnosis of mycosis fungoides (MF) or Sézary syndrome (SS)
- Relapsed or refractory disease after at least two prior courses of systemic therapy\*\*
- Mogamulizumab will be used as a single agent therapy (not to be given in combination with other systemic therapies)
- ECOG\* Performance Status 0-1
- Counseling provided to advise female patients of reproductive potential **OR** male patients and their female partners of reproductive potential to use effective contraception during treatment with mogamulizumab-kpkc and for at least 3 months following last dose of mogamulizumab-kpkc.

\* ECOG Eastern Cooperative Oncology Group; \*\* patients received 2-5 prior treatments in MAVORIC