Pembrolizumab (KETYRUDA) and Pembrolizumab and berahyaluronidase (KETRUDA QLEX) Criteria for Use May 2026

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.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive pembrolizumab.

- ☐ Autoimmune disease
- ☐ Immunosuppression including corticosteroid equivalent to >10 mg per day of prednisone
- ☐ Primary immunodeficiency
- ☐ History of allogeneic hematopoietic stem cell or solid organ transplant
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

The answers to one of the following must be fulfilled in order to meet criteria.

- ☐ Indication is FDA approved^1
- ☐ Off-label use supported by high-level published data

^1 Pembrolizumab and berahyaluronidase does not have an indication in classical Hodgkin Lymphoma or Primary Mediastinal Large B-Cell Lymphoma.

Additional Inclusion Criteria

- ☐ Care is provided by a VA/VA Community Care oncology or hematology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2
- ☐ Female patients of child-bearing potential and male patients with female partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception during therapy and for 4 months after the last dose.

Prepared: March 2016; Update September 2017, Update November 2017, Update November 2018; Update May 2021; Update May 2026. Contact: Berni Heron, Pharm.D., BCOP, or Mark Geraci, Pharm.D., BCOP National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services