I. Medication Description

Keytruda (pembrolizumab) is a human programmed death receptor-1 (PD-1) blocking antibody that binds to PD-1 on T lymphocytes, blocking the interaction of PD-1 with its ligands located on the tumor cell surface, PD-L1 and PD-L2. PD-1 ligands are often overexpressed in melanoma and some other solid tumors, contributing to inhibition of active T lymphocyte immune surveillance of tumors. Through blockade of this pathway, pembrolizumab is able to prevent T lymphocyte inactivation.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- Keytruda is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available for quantities sufficient to comply with FDA-approved dosing.

V. Coverage Duration

Coverage is granted for six months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information
• Keytruda is available as 50 mg lyophilized powder in single-use vials for reconstitution, and 100mg/4ml solution in a single use vial

• J9271: 1 billable unit = 1mg

• Pertinent indications:
  o B-Cell Lymphomas : Diffuse Large B-Cell Lymphoma- C85.20-C85.29
  o Bladder Cancer- C61, C65.1, C65.2, C65.9, C66.1, C66.2, C66.9, C67.0-C67.9, C68.0, D09.0, Z85.51, Z85.59
  o Bone Cancer (Ewing Sarcoma, Osteosarcoma)- C40.00-C40.02, C40.10-C40.12, C40.20-C40.22, C40.30-C40.32, C40.80-C40.82, C40.90-C40.92, C41.0-C41.4, C41.9, Z85.830
  o Central Nervous System Cancers- C79.31, Z85.118, Z85.82
  o Cervical Cancer- C53.0, C53.1, C53.8, C53.9, C79.89, C79.9, Z80.49
  o Colon Cancer - C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C78.00-C78.02, C78.6, C78.7, Z85.038, Z85.068
  o Esophageal and Esophagogastric Junction Cancers- C15.3-C15.5, C15.8, C15.9, C16.0, D37.8, D37.9, Z85.00, Z85.01
  o Gastric Cancer- C16.0-C16.6, C16.8, C16.9, D37.1, Z85.00, Z85.028
  o Very Advanced and Recurrent/Persistent Head and Neck Cancer - C00.0-C00.6, C00.8, C01, C02.0-C02.4, C02.8, C02.9, C03.0, C03.1, C03.9, C04.0, C04.1, C04.8, C04.9, C05.0, C05.1, C06.0, C06.2, C06.80, C06.89, C06.9, C09.0, C09.1, C09.8, C09.9, C10.3, C11.0-C11.3, C11.8, C11.9, C12, C13.0-C13.2, C13.8, C13.9, C14.0, C14.2, C14.8, C30.0, C31.0, C31.1, C32.0-C32.3, C32.8, C32.9, C44.00, C44.02, C44.09, C76.0, C77.0, C78.89, D37.01, D37.02, D37.05, D37.09, D38.0, D38.5, D38.6, Z85.21, Z85.22, Z85.810, Z85.818, Z85.819
  o Hepatobiliary Cancer (Gallbladder Cancer, Intrahepatic/Extrahepatic Cholangiocarcinoma)- C22.1, C23, C24.0, C24.1, C24.8, C24.9
  o Hodgkin Lymphoma - C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.90-C81.99, Z85.71
  o Malignant Pleural Mesothelioma- C38.4, C45.0
  o Melanoma- C43.0, C43.10-C43.12, C43.20-C43.22, C43.30, C43.31, C43.39, C43.4, C43.51, C43.52, C43.59-C43.62, C43.70-C43.72, C43.8, C43.9, C69.90-C69.92, C79.31, C80.0, C80.1, Z85.820
  o Non-Melanoma Skin Cancers (Merkel Cell Carcinoma) - C4A.0, C4A.10-C4A.12, C4A.20-C4A.22, C4A.30, C4A.31, C4A.39, C4A.4, C4A.51, C4A.52, C4A.59-C4A.62, C4A.70-C4A.72, C4A.8, C4A.9, C78.1, Z85.821
  o Neuroendocrine and Adrenal Tumors- C74.00-C74.02, C74.90-C74.92, C78.00-C78.04, C78.8, Z85.858
  o NSCLC- C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, Z85.118
  o Ovarian Cancer/Fallopian Tube Cancer/ Primary Peritoneal Cancer- C48.1, C48.2, C48.8, C56.1, C56.2, C56.9, C57.00-C57.02, C57.10-C57.12, C57.20-C57.22, C57.3, C57.4, C57.7-C57.9, Z85.43
  o Pancreatic Adenocarcinoma- C25.0-C25.3, C25.7-C25.9, Z85.07
  o Penile Cancer- C60.0, C60.1, C60.2, C60.8, C60.9, C63.7, C63.8, Z85.49
  o Prostate Cancer- C61, Z85.46
  o Rectal Cancer - C19, C20, C21.8, C78.00-C78.02, C78.7
  o T-Cell Lymphomas (Mycosis Fungoides, Extranodal NK/T-Cell nasaltyle)- C84.00-C84.09, C84.10-84.19, C84.90-C84.99, C84.20, C84.21, C84.22, C84.23, C84.24, C84.25, C84.26, C84.27, C84.28, C84.29, Z86.0
  o Testicular Cancer- C62.00-C62.02, C62.10-C62.12, C62.90-C62.92, Z85.47
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<th>Drug Therapy Guidelines</th>
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<td>o Uterine Neoplasms (Endometrial Carcinoma)- C54.0-C54.3, C54.8, C54.9, C55, Z80.49</td>
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<td>o Uveal Melanoma- C69.30-C69.32, C69.40 -C69.42, C69.60-C69.62</td>
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<td>o Vulvar Cancer (Squamous Cell Carcinoma)- C51.0-C51.2, C51.8, C51.9, C57.7, C57.8, C79.82, C79.89, C79.9</td>
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VIII. Summary of Policy Changes

- 3/15/15: new policy
- 6/15/15: policy updated to allow for first line therapy
- 7/1/15: formulary distinctions made
- 1/1/16: drug code updated
- 3/15/16: updated coverage to coincide with current NCCN treatment guidelines
- 2/3/17: policy updated to correspond with current NCCN treatment guidelines
- 4/5/17: policy updated to correspond with current NCCN treatment guidelines; billing/coding information updated
- 11/1/18: criteria coverage updated to allow use as supported by current NCCN guidelines; updated quantity limitations and billing/coding
- 11/15/19: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.