I. Medication Description

Binding of the programmed death-ligand (PD-L) found on T cells inhibits T cell proliferation and cytokine production. Upregulation of the PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to the inhibition of active T cell immune surveillance of tumors. Opdivo, an IgG4 human monoclonal antibody, binds to the PD-1 receptor and blocks its interaction with its ligands (PD-L), thus releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor response.

II. Position Statement

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

III. Policy

Coverage of Opdivo is available when the following criteria have been met:
- Member is at least
  - 12 years of age if the medication is used for colorectal cancer
  - 18 years of age for other pertinent indications AND
- The medication 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

Quantity will be limited to FDA-approved and studied dosages.

V. Coverage Duration

Coverage may be granted for 6 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

- Available as 40 mg/4 mL, 100 mg/10 mL, and 240mg/24mL solution in single-dose vials
- J9299: 1 billable unit = 1mg
- Pertinent indications:
  - Hodgkin Lymphoma: C81.10-C81.19, C81.20-C81.29, C81.30-C81.39, C81.40-C81.49, C81.90-C81.99, Z85.71
  - 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
  - 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
  - SCLC: C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92, C78.00-C78.02, C79.31, C79.51, C79.52, Z85.118
  - Renal cell carcinoma: C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528
  - Colon cancer: C17.0-C17.2, C17.8, C18.0-C18.9, C78.00-C78.02, C78.6, C78.7, Z85.038
  - Rectal cancer: C19, C20, C21.8, C78.00-C78.02, C78.7
  - 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, C06.8, 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
  - 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
  - Malignant Pleural Mesothelioma: C38.4, C45.0

### VIII. Summary of Policy Changes

- 6/15/15: new policy
- 7/1/15: formulary distinctions made, coverage extended to large cell and adenocarcinoma histologies
- 10/26/15: updated policy to reflect NCCN treatment guideline updates
- 11/24/15: updated policy to reflect new FDA-approved indication in renal cell carcinoma
- 12/15/15: no policy changes
- 1/1/16: drug code updated
- 7/11/16: updated policy to reflect NCCN treatment guideline updates
- 9/15/16: updated policy to reflect NCCN treatment guideline updates
- 2/6/17: updated policy to reflect NCCN treatment guideline updates
- 10/11/17: coverage criteria updated to allow use as supported by current NCCN guidelines; coding for bladder cancer and malignant pleural mesothelioma added
- 11/1/18: 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.