Medical benefit drug policies are a source for WyoBlue Advantage medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 02/13/2025

Nivolumab Products

Opdivo® (nivolumab)
Opdivo Qvantig™ (nivolumab and hyaluronidase-nvhy)

HCPCS: Opdivo: J9299; Opdivo Qvantig: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Treatment must follow the Food and Drug Administration (FDA) approved indications or National Comprehensive Cancer Network (NCCN) guidelines when it is a Category 1 or 2A recommendation
      i. Must be used with concomitant treatment according to FDA indication or NCCN Category 1 or 2A recommendation
   b. Must be prescribed by, or in consultation with, an oncologist or hematologist
   c. No prior failure of a programmed death receptor-1 (PD-1 or PD-L1) inhibitor
   d. Patient is not receiving therapy for a chronic condition, such as an autoimmune disease, that requires treatment with a systemic immunosuppressant

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Align with FDA recommended dosing
   b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
   c. Renewal Criteria: Treatment may be continued until unacceptable toxicity or disease progression

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Opdivo is a programmed death receptor-1 (PD-L1)-blocking antibody indicated for the following:
    - Patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab
    - For the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma
    - Adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy
    - Adult patients with metastatic non-small cell lung cancer expressing PD-L1 (≥1%) as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, as first-line treatment in combination with ipilimumab
    - Adult patients with metastatic or recurrent non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations as first-line treatment, in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy
    - Patients with metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo
    - Adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with ipilimumab
    - Patients with intermediate or poor risk advanced renal cell carcinoma, as a first-line treatment in combination with ipilimumab
    - Patients with advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib
    - Patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy
    - Adult patients with classical Hodgkin lymphoma that has relapsed or progressed after:
        - Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or
        - 3 or more lines of systemic therapy that includes autologous HSCT
    - Patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy
    - Adjuvant treatment of patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection of urothelial carcinoma
    - Patients with locally advanced or metastatic urothelial carcinoma who:
        - Have disease progression during or following platinum-containing chemotherapy

        - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

    - Adult and pediatric patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as a single agent or in combination with ipilimumab

    - Patients with hepatocellular carcinoma who have been previously treated with sorafenib in combination with ipilimumab

    - Patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy

    - Patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy.

    - Patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with ipilimumab

    - Patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy

    - Patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy

- Opdivo Qvantig is programmed death receptor-1 (PD-L1)-blocking antibody indicated for the following:

    - Adult patients with intermediate or poor risk advanced renal cell carcinoma, as a first-line treatment following combination treatment with intravenous nivolumab and ipilimumab

    - Adult patients with advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib

    - Adult patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy

    - Adult patients with unresectable or metastatic melanoma

    - Adult patients with unresectable or metastatic melanoma following combination treatment with intravenous nivolumab and ipilimumab

    - For the adjuvant treatment of adult patients with completely resected stage IIB, stage IIC, stage III, or stage IV melanoma

    - Adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer in the neoadjuvant setting, in combination with platinum-doublet chemotherapy

    - Adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer and no known EGFR mutations or ALK rearrangements, for neoadjuvant treatment, in combination with platinum-doublet chemotherapy, followed by Opdivo Qvantig monotherapy as adjuvant treatment after surgery

- Adult patients with metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Opdivo Qvantig

- Adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck with disease progression on or after a platinum-based therapy

- As adjuvant treatment of adult patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection of urothelial carcinoma

- Adult patients with unresectable or metastatic urothelial carcinoma, as first-line treatment in combination with cisplatin and gemcitabine

- Adult patients with locally advanced or metastatic urothelial carcinoma who:

    - Have disease progression during or following platinum-containing chemotherapy

    - Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

- Adult patients with MSI-H or dMMR metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, as monotherapy or as monotherapy following combination treatment with intravenous nivolumab and ipilimumab

- Adult patients with hepatocellular carcinoma previously treated with sorafenib and following combination treatment with intravenous nivolumab and ipilimumab

- Adult patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy

- Adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy

- Adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine and platinum-based chemotherapy

- Adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy

- Limitations of Use: Opdivo Qvantig is not indicated in combination with ipilimumab

- The National Comprehensive Cancer Network (NCCN) guidelines category 1 and 2A recommendations are based on uniform NCCN consensus that the recommendations are appropriate. Treatment regimens have been studied and shown to be efficacious when administered as listed in the guidelines. Category 2B and 3 recommendations do not have a high level of evidence to support use and also do not have a uniform consensus from the NCCN panel that the recommendations are appropriate.

- There are no studies to support use of Opdivo or Opdivo Qvantig following failure. NCCN treatment guidelines also do not recommend use of Opdivo or other PD-L1 checkpoint inhibitors following a previous failure.

- Opdivo and Opdivo Qvantig have not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants.

- Opdivo and Opdivo Qvantig have not been studied in patients with an ECOG performance status of greater than 2 and therefore, should not be sed in patients with an ECOG score greater than 2.

References:

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Policy History		
#	Date	Change Description
1.0	Initial Effective Date: 01/01/2026	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*