Medicare Advantage Medical Benefit Drug Policy

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Effective Date: 04/08/2021

Opdivo® (nivolumab)

FDA approval: 10/15/2014
HCPCS: J9299
Benefit: Medical

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
   e. Eastern Cooperative Oncology Group (ECOG) performance status of 0 - 2

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: Align with FDA recommended dosing
   b. Authorization Period: 6 months
   c. Renewal Criteria: No evidence of disease progression or unacceptable toxicity

***Note: Coverage 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.

Therapeutic considerations:

A. **FDA approved indication/Diagnosis**

**Please refer to most recent prescribing information.*

B. **Background Information**

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

i. Patients with unresectable or metastatic melanoma, as a single agent or in combination with ipilimumab

ii. Patients with melanoma with lymph node involvement or metastatic disease who have undergone complete resection, in the adjuvant setting

iii. 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

iv. 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

v. 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

vi. Adult patients with unresectable malignant pleural mesothelioma, as first-line treatment in combination with ipilimumab

vii. Patients with intermediate or poor risk advanced renal cell carcinoma, as a first-line treatment in combination with ipilimumab

viii. Patients with advanced renal cell carcinoma, as a first-line treatment in combination with cabozantinib

ix. Patients with advanced renal cell carcinoma who have received prior anti-angiogenic therapy

x. Adult patients with classical Hodgkin lymphoma that has relapsed or progressed after:

1. Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin, or

2. 3 or more lines of systemic therapy that includes autologous HSCT

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

xii. Patients with locally advanced or metastatic urothelial carcinoma who:

1. Have disease progression during or following platinum-containing chemotherapy

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

xiii. 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

xiv. Patients with hepatocellular carcinoma who have been previously treated with sorafenib, as a single agent or in combination with ipilimumab

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

b. 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.

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

d. Opdivo has not been studied in patients on chronic immunosuppressant therapy and therefore, should not be used in patients on chronic immunosuppressants.

e. Opdivo has 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.

C. **Efficacy**

**Please refer to most recent prescribing information.*

D. **Medication Safety Considerations**

**Please refer to most recent prescribing information.*

E. **Dosing and administration**

**Please refer to most recent prescribing information.*

F. **How supplied**

**Please refer to most recent prescribing information.*

References:

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4. Larkin J, Chiarion-Sileni V, Gonzalez R, et al. Combined nivolumab and ipilimumab or monotherapy in untreated melanoma. NEJM. 2015 Jul 2; 373 (1): 23 - 34.
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16. National Comprehensive Cancer Network. Bladder cancer (Version 6.2020). 2020 July 16. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed on February 9, 2021.
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Policy History		
#	Date	Change Description
1.1	Effective Date: 04/08/2021	Updated to remove the renewal authorization period and only allow for a 6 months approval at a time.
1.0	Effective Date: 04/16/2020	Medical Policy established

** 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.*