

## SPECIALTY GUIDELINE MANAGEMENT

### OPDIVO (nivolumab)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### A. FDA-Approved Indications

1. Unresectable or metastatic melanoma
  - i. As a single agent for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.
  - ii. As a single agent for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.
  - iii. In combination with ipilimumab for the treatment of patients with unresectable or metastatic melanoma.
2. Adjuvant treatment of melanoma  
Opdivo is indicated for the adjuvant treatment of melanoma with lymph node involvement or metastatic disease who have undergone complete resection
3. Metastatic non-small cell lung cancer (NSCLC)  
Opdivo is indicated for the treatment of patients with metastatic NSCLC with 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.
4. Renal cell carcinoma (RCC)
  - i. Opdivo is indicated for the treatment of patients with advanced RCC who have received prior anti-angiogenic therapy.
  - ii. Opdivo is indicated for the treatment of patients with intermediate or poor risk, previously untreated advanced renal cell carcinoma, in combination with ipilimumab.
5. Classical Hodgkin lymphoma (cHL)  
Opdivo is indicated for the treatment of patients with cHL that has relapsed or progressed after:
  - i. Autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin
  - ii. 3 or more lines of therapy that includes autologous HSCT
6. Squamous Cell Carcinoma of the Head and Neck  
Opdivo is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.
7. Urothelial Carcinoma  
Opdivo is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:
  - i. Have disease progression during or following platinum-containing chemotherapy

<b>Reference number(s)</b>
1894-A

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

8. **Colorectal Cancer**

Opdivo is indicated for adult and pediatric (12 years and older) patients with microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

9. **Hepatocellular Carcinoma**

Opdivo is indicated for the treatment of hepatocellular carcinoma who have been previously treated with sorafenib.

B. **Compendial Uses**

1. Classical Hodgkin lymphoma
2. Renal cell carcinoma
3. Malignant pleural mesothelioma
4. NSCLC
5. Small cell lung cancer

All other indications are considered experimental/investigational and are not a covered benefit.

**II. CRITERIA FOR INITIAL APPROVAL**

**A. Unresectable or metastatic melanoma**

Authorization of 12 months may be granted for the treatment of unresectable or metastatic melanoma.

**B. Adjuvant treatment of melanoma**

Authorization of 12 months may be granted for the adjuvant treatment of melanoma with lymph node involvement or metastatic disease who have undergone complete resection

**C. Non-small cell lung cancer (NSCLC)**

Authorization of 12 months may be granted for treatment of metastatic NSCLC when Opdivo is requested for disease progression on or after a first-line cytotoxic regimen or for further progression on other systemic therapy.

**D. Renal cell carcinoma**

Authorization of 12 months may be granted for treatment of advanced, relapsed or unresectable renal cell carcinoma.

**E. Classical Hodgkin lymphoma (cHL)**

Authorization of 12 months may be granted for treatment of cHL.

**F. Squamous cell carcinoma of the head and neck (SCCHN)**

Authorization of 12 months may be granted for treatment of recurrent or metastatic SCCHN in members with disease progression on or after platinum-based therapy.

**G. Urothelial carcinoma**

Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma when any of the following criteria is met:

1. Member experienced disease progression during or following platinum-containing chemotherapy.

<b>Reference number(s)</b>
1894-A

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

**H. Colorectal cancer**

Authorization of 12 months may be granted for treatment of unresectable locally advanced or metastatic colorectal cancer with defective mismatch repair or high microsatellite instability.

**I. Malignant pleural mesothelioma**

Authorization of 12 months may be granted for treatment of malignant pleural mesothelioma

**J. Small cell lung cancer**

Authorization of 12 months may be granted for treatment of small cell lung cancer.

**K. Hepatocellular carcinoma**

Authorization of 12 months may be granted for treatment of hepatocellular carcinoma for members who have been previously treated with sorafenib.

**III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**IV. REFERENCES**

1. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; April 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed January 10<sup>th</sup> 2018.