Reference number(s)
1894-A

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 (Bladder cancer, Upper Genitourinary tract tumors, Urothelial carcinoma of the prostate, Primary carcinoma of the urethra)
   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

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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, as a single agent or in combination with ipilimumab.

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

10. Small cell lung cancer
    Opdivo is indicated for the treatment of patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.

B. Compendial Uses
   1. Classical Hodgkin lymphoma
   2. Colorectal cancer
   3. Renal cell carcinoma (Kidney cancer)
   4. Non-small cell lung cancer (NSCLC)
   5. Small cell lung cancer
   6. Uveal Melanoma
   7. Anal Carcinoma
   8. Merkel Cell Carcinoma
   9. Central Nervous System (CNS) brain metastases in patients with melanoma

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 (Kidney cancer)
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.

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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 (Bladder cancer, Upper Genitourinary tract tumors, Urothelial carcinoma of the prostate, Primary carcinoma of the urethra)
Authorization of 12 months may be granted for treatment of locally advanced or metastatic urothelial carcinoma, including bladder cancer, upper genitourinary tract tumors, urothelial carcinoma of the prostate, or primary carcinoma of the urethra, when the member has experienced disease progression following platinum-containing chemotherapy.

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

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

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

K. Uveal Melanoma
Authorization of 12 months may be granted for treatment of uveal melanoma.

L. Anal Carcinoma
Authorization of 12 months may be granted for treatment of anal cancer.

M. Merkel Cell Carcinoma
Authorization of 12 months may be granted for treatment of Merkel cell carcinoma.

N. CNS Brain Metastases
Authorization of 12 months may be granted for treatment of CNS brain metastases in patients with melanoma.

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; August 2018.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed July 25, 2018.

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