Reference number(s)
3853-A

JURISDICTION SPECIFIC MEDICARE PART B

OPDIVO (nivolumab)

POLICY

I. COVERED USES

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

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Unresectable or metastatic melanoma
B. Adjuvant treatment of melanoma
C. Neoadjuvant treatment of resectable non-small cell lung cancer
D. Metastatic non-small cell lung cancer
E. Advanced renal cell carcinoma
F. Classical Hodgkin lymphoma
G. Squamous cell carcinoma of the head and neck
H. Urothelial carcinoma
I. Microsatellite instability-high or mismatch repair deficient metastatic colorectal cancer
J. Hepatocellular carcinoma
K. Esophageal squamous cell carcinoma
L. Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma
M. Cutaneous melanoma
N. Non-small cell lung cancer
O. Colorectal cancer
P. Kidney cancer
Q. Head and neck cancer
R. Uveal melanoma
S. Anal carcinoma
T. Merkel cell carcinoma
U. Malignant pleural mesothelioma
V. Gestational trophoblastic neoplasia
W. Small bowel adenocarcinoma, including advanced ampullary cancer
X. Extranodal NK/T-cell lymphoma, nasal type
Y. Vulvar cancer
Z. Uterine neoplasms/Endometrial carcinoma
AA. Esophageal and esophagogastric junction cancers
BB. Cervical cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration.

III. CRITERIA FOR APPROVAL

A. Cutaneous Melanoma
Authorization of 12 months may be granted for treatment of cutaneous melanoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

B. Non-Small Cell Lung Cancer
1. Authorization of 3 months may be granted for neoadjuvant treatment of non-small cell lung cancer.
2. Authorization of 12 months may be granted for treatment of non-small cell lung cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

C. Colorectal Cancer
Authorization of 12 months may be granted for treatment of colorectal cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

D. Urothelial Carcinoma
Authorization of 12 months may be granted for treatment of urothelial carcinoma, including bladder cancer, upper genitourinary tract tumors, urothelial carcinoma of the prostate, and primary carcinoma of the urethra unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

E. Kidney Cancer
Authorization of 12 months may be granted for treatment of kidney cancer, including renal cell carcinoma, unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

F. Head and Neck Cancer
Authorization of 12 months may be granted for treatment of head and neck cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

G. Classical Hodgkin Lymphoma
Authorization of 12 months may be granted for treatment of classical Hodgkin lymphoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

H. **Hepatocellular Carcinoma**
Authorization of 12 months may be granted for treatment of hepatocellular carcinoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

I. Esophageal and Esophagogastric Junction Cancers
Authorization of 12 months may be granted for treatment of esophageal and esophagogastric junction cancers unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

J. Uveal Melanoma
Authorization of 12 months may be granted for treatment of uveal melanoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

K. Anal Carcinoma
Authorization of 12 months may be granted for treatment of anal carcinoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

L. Merkel Cell Carcinoma
Authorization of 12 months may be granted for treatment of Merkel cell carcinoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

M. Malignant Pleural Mesothelioma
Authorization of 12 months may be granted for treatment of malignant pleural mesothelioma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

N. Gestational trophoblastic neoplasia
Authorization of 12 months may be granted for treatment of gestational trophoblastic neoplasia unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

O. Small Bowel Adenocarcinoma
Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma, including ampullary cancer, unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

P. Extranodal NK/T-cell Lymphoma, Nasal Type
Authorization of 12 months may be granted for treatment of nasal-type extranodal NK/T-cell lymphoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

Q. Vulvar Cancer
Authorization of 12 months may be granted for treatment of vulvar cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

R. Uterine Neoplasms/Endometrial Carcinoma
Authorization of 12 months may be granted for treatment of uterine neoplasms or endometrial carcinoma unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

S. **Gastric Cancer**
Authorization of 12 months may be granted for treatment of gastric cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

T. **Cervical Cancer**

Authorization of 12 months may be granted for treatment of cervical cancer unless the disease progressed while receiving treatment with another PD-1 directed agent (e.g., pembrolizumab).

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R14. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
2. Billing and Coding: Nivolumab (A54862) Version R23. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 16, 2022.
4. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb; March 2022.
5. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 14, 2022.

