

Nivolumab

(Opdivo®) J9299 (1mg)

Covered with prior authorization

Nivolumab (Opdivo®) may be authorized when the following criteria are met:

- Prescriber is an oncology practitioner.
- AND**
- For a FDA-approved indication or indication supported by national guidelines, such as National Comprehensive Cancer Network (NCCN).
- AND**
- Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.
- AND**
- Diagnosis of metastatic anal carcinoma; **AND**
- Individual is NOT using as first line therapy; **AND**
- Individual is using as a single agent; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.
- OR**
- Diagnosis of metastatic or unresectable bone cancer; **AND**
- Individual is NOT using as first line therapy; **AND**
- Individual is using in combination with ipilimumab; **AND**
- Individual has no alternative treatment if tissue tumor mutation burden-high (TMB-H) tumors has 10 or more mutations per megabase; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.
- OR**
- Diagnosis of biliary tract cancer; **AND**
- Individual is NOT using as first line therapy OR resected gross residual (R2) disease OR metastatic disease with TMB-H; **AND**
- Individual is using in combination with ipilimumab; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.
- OR**
- Diagnosis of cervical cancer; **AND**
- Individual is NOT using as first line therapy; **AND**
- Individual is using as a single agent; **AND**
- Individual has CPS > 1 for local/regional recurrence OR stage IVB OR recurrence with distance metastases; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.

OR

- Diagnosis of Classical Hodgkin lymphoma (cHL) for:
- Adult and pediatric (12 years and older) patients with previously untreated, stage III or IV cHL in combination with doxorubicin, vinblastine, and dacarbazine (AVD); **OR**
- 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.

OR

- Diagnosis of Colorectal Cancer; **AND**
- Individual is 12 years or older, and has unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in combination with ipilimumab; **OR**
- Individual is 12 years or older, and has with MSI-H or dMMR metastatic colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan;

AND

- Individual has not received another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual has a current ECOG performance status of 0-2.

OR

- Diagnosis of unresectable locally advanced, recurrent, or metastatic Esophageal Squamous Cell Carcinoma (ESCC); **AND**
 - Individual is using as single agent OR in combination with ipilimumab for second line or subsequent therapy; **AND**
 - Individual has confirmation of disease progression on or had intolerance to fluoropyrimidine- and platinum-based chemotherapy; **OR**
 - Individual is using with ipilimumab OR with fluoropyrimidine and platinum therapy for first line treatment; **AND**
- Individual has a current ECOG performance status of 0-2 or Karnofsky performance score of 60-100; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.

OR

- Diagnosis of completely resected Esophageal or Gastroesophageal Junction Cancer; **AND**
- Individual is using as single agent for residual pathologic disease; **AND**
- Individual has received neoadjuvant chemoradiotherapy (CRT); **AND**
- Individual has a current ECOG performance status of 0-2; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.

OR

- Diagnosis of advanced or metastatic Gastric, Gastroesophageal Junction Cancer, or Esophageal Adenocarcinoma; **AND**
- Individual is using in combination with fluoropyrimidine and platinum-containing chemotherapy; **AND**
- Individual has HER-2 negative disease; **AND**
- Individual has a current ECOG performance status of 0-2; **AND**
- Individual has not received treatment with another anti-PD-1, anti-PD-L1 agent, or other checkpoint inhibitor.

OR

- Diagnosis of advanced or metastatic Gastric, Gastroesophageal Junction Cancer, or Esophageal Adenocarcinoma; **AND**
- Individual has microsatellite instability-high (MSI-H) OR deficient mismatch repair (dMMR) tumor; **AND**
 - Individual is using as a single agent in individuals that previously received therapy with nivolumab + ipilimumab; **OR**
 - Individual is using in combination with ipilimumab; **OR**
 - Individual is using in combination with fluoropyrimidine- and platinum-based chemotherapy.

OR

- Diagnosis of intermediate to high-risk disease multi-agent chemotherapy-resistant gestational trophoblastic neoplasia; **AND**
- Individual is using as a single agent; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of advanced Hepatocellular Carcinoma (HCC); **AND**
- Individual is using in combination with ipilimumab for subsequent therapy **OR** progressive disease with Child-Pugh Class A; **AND**
- Individual has a ECOG performance status of 0-2; **AND**
- Individual does not have multicentric Castleman Disease (MCD) or KSHV-associated inflammatory cytokine syndrome (KICS).

OR

- Diagnosis of relapsed/refractory advanced classic Kaposi Sarcoma; **AND**
- Individual is NOT using as first line therapy; **AND**
- Individual is using in combination with ipilimumab; **AND**
-
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of unresectable Malignant Pleural or Peritoneal Mesothelioma; **AND**
 - Using as first line therapy in combination with ipilimumab (Yervoy); **OR**
 - Using as subsequent therapy as a single agent; **OR**
 - Using as subsequent therapy in combination with ipilimumab (Yervoy); **AND**
- Individual is using in combination with ipilimumab (Yervoy); **AND**
- Individual has a ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Melanoma (Cutaneous or Uveal); **AND**
- Individual has unresectable or metastatic melanoma; **AND**
- **One** of the following:
 - Using as first-line therapy for untreated melanoma
 - as a single agent; **OR**
 - in combination with ipilimumab; **OR**
 - Using as second-line or subsequent therapy for confirmed disease progression while receiving or since completing most recent therapy or has lymph node involvement
 - as a single agent; **OR**
 - in combination with ipilimumab; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of resected advanced Melanoma; **AND**
- Individual is using as a single agent for up to 12 months of adjuvant therapy; **AND**
- Individual has resected stage IIB, stage IIC, stage III, or stage IV disease; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of metastatic Melanoma with brain metastases; **AND**
 - Individual has a primary diagnosis of melanoma; **AND**
 - Individual has asymptomatic brain metastases OR Individual has BRAF non-specific asymptomatic brain metastases; **AND**
 - Individual is using as monotherapy or in combination with ipilimumab; **AND**
 - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Merkel Cell Carcinoma; **AND**
- Individual is using as a single agent or in combination with ipilimumab; **AND**
- Individual has presence of metastatic or recurrent locoregional MCC determined to be not amenable to definitive surgery or radiation therapy; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Non-Small Cell Lung Cancer (NSCLC) and the following criteria are met:
- Individual has metastatic NSCLC; **AND**
- Individual is using as a single agent; **AND**
- Confirmation of disease progression on or after platinum-containing chemotherapy; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- Individual is not receiving therapy for an autoimmune disease, chronic condition, or interstitial lung disease with a systemic immunosuppressant.

OR

- Diagnosis of recurrent, advanced, or metastatic NSCLC; **AND**
- Using as first-line therapy; **AND**
- Individual is using in combination with ipilimumab; **AND**
- Individual does not have presence of actionable molecular markers; **AND**

- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of recurrent or metastatic NSCLC; **AND**
- Using as first-line therapy; **AND**
- Individual is using in combination with ipilimumab *and* 2 (two) cycles of platinum-doublet chemotherapy (i.e., platinum-based chemotherapy with pemetrexed, or carboplatin with paclitaxel); **OR**
- Individual is using for continuation treatment with ipilimumab post chemotherapy **AND**
- Individual does not have presence of actionable molecular markers; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of resectable NSCLC; **AND**
- Individual is using in combination with double platinum chemotherapy; **AND**
- Resectable tumor is ≥ 4 cm OR node positive; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of metastatic NSCLC with brain metastases; **AND**
- Individual has a primary diagnosis of non-small cell lung cancer; **AND**
- Individual is using as single agent for brain metastases; **AND**
- Individual has PD-L1 expression positive ($\geq 1\%$) tumors; **AND**
- Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Renal Cell Carcinoma (RCC); **AND**
- Individual has **advanced or metastatic** RCC; **AND**
 - Individual is using as monotherapy; **AND**
 - Histological confirmation of RCC with clear-cell component; **AND**
 - Individual has confirmation of disease progression after one or two prior anti-angiogenic regimens (e.g. axitinib, bevacizumab [or bevacizumab biosimilar], pazopanib, sorafenib, sunitinib, etc.) for treatment of advanced or metastatic disease; **AND**
 - Current ECOG performance status of 0-2; **AND**
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **OR**
- Individual has **intermediate- or poor-risk, advanced** RCC; **AND**
 - Using as first-line therapy for previously untreated RCC in combination with ipilimumab for four cycles followed by single agent Opivido® (nivolumab); **OR**
 - Using as subsequent therapy, if no checkpoint blockade (PD-1, PD-L1, or CTLA-4) antibody treatment has been previously administered in combination with ipilimumab for four cycles followed by single agent Opivido® (nivolumab); **AND**
 - Histological confirmation of RCC with clear-cell component; **AND**
 - Current ECOG performance status of 0-2; **AND**
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **OR**
- Individual has **relapsed, recurrent, or advanced** RCC; **AND**
 - Individual is using as first-line therapy in combination with cabozantinib tablets; **OR**
 - Individual is using as subsequent therapy in combination with cabozantinib tablets after prior oncology therapy (e.g. pembrolizumab) **AND**

- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.
- Individual has **relapsed or metastatic** non-clear cell RCC; **AND**
 - Individual is using as a single agent OR in combination with cabozantinib;
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Small Bowel Adenocarcinoma (SBA); **AND**
 - Individual has advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] only); **AND**
 - Individual is using subsequent therapy; **AND**
 - As monotherapy; **OR**
 - In combination with ipilimumab; **AND**
 - Current ECOG performance status of 0-2; **AND**
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of relapsed/refractory Extranodal NK/T-cell lymphomas; **AND**
- Individual has tried and failed asparaginase-based treatment; **AND**
- Individual is using as monotherapy; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of advanced or metastatic Soft Tissue Sarcoma and Aggressive Soft Tissue Neoplasms; **AND**
- Individual is using as monotherapy; **OR**
- Individual is using in combination with ipilimumab; **AND**

Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Squamous Cell Carcinoma of the Head and Neck (SCCHN); **AND**
 - Individual has recurrent, unresectable, or metastatic SCCHN; **AND**
 - Individual is using as monotherapy; **AND**
 - Individual has confirmation of disease progression on or after platinum-containing chemotherapy; **AND**
 - Current ECOG performance status of 0-2; **AND**
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of recurrent, Squamous Cell Carcinoma of the Head and Neck (SCCHN); **AND**
 - Individual has recurrent, unresectable, or metastatic nasopharyngeal; **AND**
 - Individual is not able to use surgery or radiotherapy; **AND**
 - Individual is using in combination with cisplatin and gemcitabine; **AND**
 - Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of recurrent, Squamous Cell Carcinoma of the Head and Neck (SCCHN); **AND**
 - Individual has squamous recurrent, unresectable, or metastatic non-nasopharyngeal cancer; **AND**
 - Individual is not able to use surgery or radiotherapy; **AND**
 - Individual is using in combination with cetuximab.

OR

- Diagnosis of Urothelial Carcinoma; **AND**
 - Individual has locally advanced or metastatic disease; **AND**
 - Individual is using as a single agent; **AND**
 - Meets **one** of the following:
 - Confirmation of disease progression on or after platinum-containing chemotherapy; **OR**
 - Confirmation of disease progression within 12 months of receiving neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;

OR

- Diagnosis of Urothelial Carcinoma; **AND**
 - Individual is using as single agent for adjuvant therapy; **AND**
 - Individual is at high risk of recurrence after having radical resection; **OR**
 - Individual is using as first-line treatment in combination with cisplatin and gemcitabine; **AND**
- Current ECOG performance status of 0-2; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of Central Nervous System Cancers- Pediatric Diffuse High-Grade Gliomas; **AND**
- Individual is using as a single agent; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

OR

- Diagnosis of recurrent or metastatic Vulvar Cancer; **AND**
- Individual is using as a single agent; **AND**
- Individual is NOT using as first line therapy; **AND**
- Individual has a tumor that is HPV-related; **AND**
- Has not received treatment with another anti-PD-1 or anti-PD-L1 agent.

AND

- Dosing by indication is supported by FDA or national standard of care protocols at the time the request is submitted.

Exclusion criteria:

Requests may not be approved for the following:

- Opdivo® (Nivolumab) may not be approved when the above criteria are not met and for all other indications;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

Initial authorization is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Opdivo® is a programmed death receptor-1 (PD-1)-blocking antibody and has the following FDA approved indications:

- Melanoma
- Non-Small Cell Lung Cancer (NSCLC)
- Malignant Pleural Mesothelioma
- Renal Cell Carcinoma (RCC)
- Classical Hodgkin Lymphoma (cHL)
- Squamous Cell Carcinoma of the Head and Neck (SCCHN)
- Urothelial Carcinoma
- Colorectal Cancer
- Hepatocellular Carcinoma (HCC)
- Esophageal Cancer
- Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

References:

Bristol-Myers-Squibb. (2021). *Opdivo® (nivolumab)* [prescribing information]. New York, NY.

<https://www.opdivo.com>

Nivolumab (Opdivo®). (2026). National Comprehensive Cancer Network, Inc. (Copyright © National Comprehensive Cancer Network, Inc). *NCCN Guidelines: Treatment by Cancer Type*. NCCN Clinical Practice Guidelines in Oncology. Retrieved May 6, 2026, from

<https://www.nccn.org/compendia-templates/nccn-templates-main/browse-by-cancer-type>

OPDIVO® (nivolumab) Label. (2022, March). Accessdata.fda.gov. Retrieved April 23, 2022, from

https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125554s112lbl.pdf

Criteria History/ Revision Information:

Date	Summary of Changes
April 2021	Pembrolizumab and Nivolumab Clinical Opportunities developed by Ascension Hematology and Oncology Expert Review Panel
May 2021	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group
August 2023	Revised criteria for use summary approved by Ascension Medical Specialty Prior Authorization Team
August 2023	Criteria for use summary revised by the Ascension Hematology/Oncology Expert Review Panel.
October 2023	Criteria for use summary approved by Ascension Therapeutic Affinity Group
December 2024	Criteria for use summary updated by the Ascension Medical Specialty Prior Authorization

	Team.
February 2025	Revised criteria for use summary approved by the Ascension Medication Specialty Prior Authorization Expert Review Panel.
April 2025	Criteria for use summary approved by Ascension Therapeutic Affinity Group
May 2026	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
June 2026	Criteria for use summary approved by Ascension Medical Policy Technology and Assessment Committee (MPTAC)
July 2026	Criteria for use summary approved by Ascension Therapeutic Affinity Group
August 2026	Annual review completed. No changes.