

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Opdivo Prior Authorization Policy

- Opdivo® (nivolumab intravenous infusion – Bristol-Myers Squibb)

REVIEW DATE: 02/08/2023

OVERVIEW

Opdivo, a human programmed death receptor-1 (PD-1) blocking antibody, is indicated for the following uses:¹

- **Classical Hodgkin lymphoma**, for adults who have relapsed or progressed after autologous hematopoietic stem cell transplantation (auto-HSCT) and Adcetris® (brentuximab vedotin intravenous infusion) OR three or more lines of systemic therapy that includes auto-HSCT.*
- **Colorectal cancer**, with or without Yervoy® (ipilimumab intravenous infusion) for patients ≥ 12 years of age with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic disease that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.*
- **Esophageal carcinoma**, in the following situations:
 - For patients with unresectable advanced, recurrent, or metastatic squamous cell disease after prior fluoropyrimidine- and platinum-based chemotherapy.
 - Adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in patients who have received neoadjuvant chemoradiotherapy.
 - First-line treatment of adults with unresectable advanced or metastatic esophageal squamous cell carcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy.
 - First-line treatment of adults with unresectable advanced or metastatic esophageal squamous cell carcinoma in combination with Yervoy.
- **Gastric cancer, esophagogastric junction cancer, and esophageal adenocarcinoma**, for patients with advanced or metastatic disease, in combination with fluoropyrimidine- and platinum-containing chemotherapy.
- **Head and neck squamous cell carcinoma**, in patients with recurrent or metastatic disease with disease progression on or after platinum-based therapy.
- **Hepatocellular carcinoma**, in patients who have been previously treated with Nexavar® (sorafenib tablets), in combination with Yervoy.*
- **Malignant pleural mesothelioma**, for first-line treatment, in combination with Yervoy in adults with unresectable disease.
- **Melanoma**, in patients with:
 - Unresectable or metastatic disease as a single agent.
 - Unresectable or metastatic disease in combination with Yervoy.
 - Adjuvant treatment for lymph node involvement or metastatic disease in patients who have undergone complete resection.
- **Non-small cell lung cancer:**
 - As first-line treatment in combination with Yervoy, in adults with metastatic disease expressing programmed death-ligand 1 (≥ 1%) as determined by an FDA-approved test, without epidermal growth factor receptor (*EGFR*) or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations.

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- As first-line treatment in combination with Yervoy and two cycles of platinum-doublet chemotherapy, in adults with recurrent or metastatic disease without *EGFR* or *ALK* genomic tumor aberrations.
- In patients with metastatic disease 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.
- In combination with platinum-doublet chemotherapy, as neoadjuvant treatment of adults with resectable (tumors \geq 4 cm or node positive) disease.
- **Renal cell carcinoma:**
 - In patients with advanced disease who have received prior anti-angiogenic therapy.
 - In combination with Yervoy, for patients with intermediate or poor risk and previously untreated advanced disease.
 - In combination with Cabometyx[®] (cabozantinib tablets), for the first-line treatment of patients with advanced disease.
- **Urothelial carcinoma**, in the following situations:
 - In patients with advanced or metastatic disease who have disease progression during or following platinum-containing chemotherapy.
 - In patients with advanced or metastatic disease who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - Adjuvant treatment of patients at high risk of recurrence after undergoing radical resection of urothelial carcinoma.

* This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Opdivo. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Opdivo as well as the monitoring required for adverse events and long-term efficacy, approval requires the medication to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Opdivo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Classic Hodgkin Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

Note: For pediatric patients, see Pediatric Hodgkin Lymphoma criteria.

A) Patient is \geq 18 years of age; AND

B) Patient meets one of the following conditions (i, ii, iii, or iv):

- i. Patient has had a hematopoietic stem cell transplantation (HSCT); OR

- ii. Patient has tried three or more systemic regimens AND this includes an auto-HSCT as one line of therapy; OR
Note: Examples are ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine), Sanford V (doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, and prednisone), escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone).
 - iii. Patient has relapsed or refractory disease and the medication is used in combination with Adcetris (brentuximab intravenous infusion) or ICE (ifosfamide, carboplatin, and etoposide); OR
 - iv. Patient is not eligible for transplant according to the prescriber; AND
- C) The medication is prescribed by or in consultation with an oncologist.
- 2. Colon, Rectal, or Appendiceal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 12 years of age; AND
 - B) The tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
 - C) Patient meets one of the following (i, ii, or iii):
 - i. Patient has tried chemotherapy; OR
Note: Examples of chemotherapy are fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine, oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
 - ii. Patient has unresectable, advanced, or metastatic disease; OR
 - iii. The medication is used for neoadjuvant therapy; AND
 - D) The medication is prescribed by or in consultation with an oncologist.
- 3. Esophageal and Esophagogastric Junction Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i, ii, iii, or iv):
 - i. Patient meets BOTH of the following (a and b):
 - a) Patient has received preoperative chemotherapy; AND
Note: Examples of chemotherapy include 5-fluorouracil plus either cisplatin or oxaliplatin; and paclitaxel plus carboplatin.
 - b) According to the prescriber, the patient has residual disease; OR
 - ii. Patient meets ALL of the following (a, b, and c):
 - a) Patient has squamous cell carcinoma; AND
 - b) Patient meets ONE of the following criteria [(1) or (2)]:
 - (1) According to the prescriber, the patient is not a surgical candidate; OR
 - (2) Patient has unresectable locally advanced, recurrent, or metastatic disease; AND
 - c) Patient has tried chemotherapy; OR
Note: Examples of chemotherapy include fluoropyrimidines (5-fluorouracil [5-FU] and capecitabine) plus either cisplatin or oxaliplatin, paclitaxel plus carboplatin, or cisplatin plus either docetaxel or paclitaxel.
 - iii. Patient meets ALL of the following (a, b, c, d, and e):
 - a) Patient has adenocarcinoma; AND
 - b) Patient meets ONE of the following criteria [(1) or (2)]:
 - (1) According to the prescriber, the patient is not a surgical candidate; OR
 - (2) Patient has unresectable locally advanced, recurrent, or metastatic disease; AND
 - c) The disease is negative for human epidermal growth factor receptor 2 (HER2) overexpression; AND

- d) The tumor expression for programmed death ligand-1 (PD-L1) has a combined positive score (CPS) ≥ 5 ; AND
 - e) The medication is used in combination with fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin; OR
 - iv. Patient meets ALL of the following (a, b, c, d, and e):
 - a) Patient has squamous cell carcinoma; AND
 - b) Patient meets ONE of the following [(1) or (2)]:
 - (1) According to the prescriber, the patient is not a surgical candidate; OR
 - (2) Patient has unresectable locally advanced, recurrent, or metastatic disease; AND
 - c) The disease is negative for human epidermal growth factor receptor 2 (HER2) overexpression; AND
 - d) The medication will be used for first-line therapy; AND
 - e) The medication will be used in combination with ONE of the following [(1) or (2)]:
 - (1) Fluoropyrimidine and platinum containing chemotherapy; OR
 - Note: Examples of fluoropyrimidines include 5-fluorouracil and capecitabine and examples of platinum agents include cisplatin and carboplatin.
 - (2) Yervoy (ipilimumab intravenous infusion); AND
 - C) The medication is prescribed by or in consultation with an oncologist.
4. **Gastric Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. Patient has unresectable locally advanced, recurrent, or metastatic disease; OR
 - ii. According to the prescriber, the patient is not a surgical candidate; AND
 - C) The disease is negative for human epidermal growth factor receptor 2 (HER2) overexpression; AND
 - D) The tumor expression for programmed death ligand-1 (PD-L1) has a combined positive score (CPS) ≥ 5 ; AND
 - E) The medication is used in combination with fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin; AND
 - F) The medication is prescribed by or in consultation with an oncologist.
5. **Head and Neck Squamous Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. Patient has non-nasopharyngeal disease; OR
 - ii. Patient meets ALL of the following conditions (a, b, and c):
 - a) Patient has nasopharyngeal disease; AND
 - b) Patient has recurrent, unresectable, oligometastatic, or metastatic disease; AND
 - c) Opdivo is used in combination with cisplatin and gemcitabine; AND
 - C) The medication is prescribed by or in consultation with an oncologist.
6. **Hepatocellular Carcinoma, Including Hepatobiliary Cancers.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has tried at least one tyrosine kinase inhibitor; AND
 - Note: Examples are Nexavar (sorafenib tablets), Lenvima (lenvatinib capsules).
 - C) The medication is prescribed by or in consultation with an oncologist.
7. **Melanoma.** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):

Note: This includes cutaneous melanoma, brain metastases due to melanoma, and uveal melanoma.

- A) Patient is ≥ 18 years of age; AND
- B) Patient meets ONE of the following (i or ii):
- i. Approve for 1 year if the patient has unresectable, advanced, or metastatic melanoma; OR
 - ii. Approve for up to 1 year of treatment (total) if Opdivo will be used as adjuvant treatment; AND
Note: Examples are in a patient with no evidence of disease following resection of node-positive disease, locoregional recurrence, or in-transit recurrence.
- C) The medication is prescribed by or in consultation with an oncologist.
- 8. Mesothelioma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 18 years of age; AND
- B) Patient has ONE of the following (i, ii, iii, or iv):
- i. Malignant pleural mesothelioma; OR
 - ii. Malignant peritoneal mesothelioma; OR
 - iii. Pericardial mesothelioma; OR
 - iv. Tunica vaginalis testis mesothelioma; AND
- C) If used as first-line therapy, the patient meets the following (i and ii):
- i. The patient has unresectable disease; AND
 - ii. The medication is used in combination with Yervoy (ipilimumab intravenous infusion); AND
- D) The medication is prescribed by or in consultation with an oncologist.
- 9. Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient is ≥ 18 years of age; AND
- B) Patient meets one of the following (i, ii, iii, iv, v, or vi):
- i. Opdivo is used as first-line or continuation maintenance therapy and the patient meets ALL of the following (a, b, and c):
Note: This is regardless of programmed death-ligand-1 (PD-L1) status.
 - a) Patient has recurrent, advanced, or metastatic disease; AND
 - b) Opdivo will be used in combination with Yervoy (ipilimumab intravenous infusion); AND
 - c) The tumor is negative for actionable mutations; OR
Note: Examples of actionable mutations include sensitizing epidermal growth factor receptor (*EGFR*) mutation, anaplastic lymphoma kinase (*ALK*) fusions, *NTRK* gene fusion-positive, *ROS1*, *BRAF V600E*, *MET 14* skipping mutation, *RET* rearrangement.
 - ii. Opdivo is used as first-line therapy and the patient meets ALL of the following (a, b, and c):
Note: This is regardless of PD-L1 status.
 - a) Patient has recurrent, advanced, or metastatic disease; AND
 - b) The tumor is positive for one of the following mutations [(1), (2), (3), or (4)]:
 - (1) *BRAF V600E* mutation; OR
 - (2) *NTRK1/2/3* gene fusion; OR
 - (3) *MET* exon 14 skipping mutation; OR
 - (4) *RET* rearrangement; AND
 - c) The medication will be used in combination with Yervoy (ipilimumab intravenous infusion); OR
 - iii. Opdivo is used as first-line or subsequent therapy and the patient meets ALL of the following (a, b, and c):
Note: This is regardless of PD-L1 status.
 - a) Patient has recurrent, advanced, or metastatic disease; AND
 - b) The tumor is positive for one of the following mutations [(1), (2), or (3)]:
 - (1) Epidermal growth factor receptor (*EGFR*) exon 20 mutation; OR
 - (2) *KRAS G12C* mutation; OR

- 11. Urothelial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. Patient has tried at least one other chemotherapy regimen; OR
Note: Examples of chemotherapy regimens are cisplatin, carboplatin, gemcitabine.
 - ii. Patient is at high risk of recurrence after radical resection of the tumor; AND
 - C) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

- 12. Ampullary Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease; AND
 - C) Patient meets ONE of the following (i or ii):
 - i. The medication is used first-line and the patient has ONE of the following conditions (a, b, or c):
 - a) Unresectable localized disease; OR
 - b) Stage IV resected disease; OR
 - c) Metastatic disease at initial presentation; OR
 - ii. The medication is used for subsequent therapy; AND
 - D) The medication is used in combination with Yervoy (ipilimumab intravenous infusion); AND
 - E) The medication is prescribed by or in consultation with an oncologist.
- 13. Anal Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has tried at least one chemotherapy regimen; AND
Note: Examples of chemotherapy are 5-fluorouracil (5-FU), cisplatin, carboplatin plus paclitaxel, FOLFOX (oxaliplatin, leucovorin, and 5-FU).
 - C) The medication is prescribed by or in consultation with an oncologist.
- 14. Bone Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, F, G, and H):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has one of the following conditions (i, ii, iii, iv, or v):
 - i. Chondrosarcoma; OR
 - ii. Chordoma; OR
 - iii. Ewing sarcoma; OR
 - iv. Osteosarcoma; OR
 - v. High-grade undifferentiated pleomorphic sarcoma; AND
 - C) Patient has unresectable or metastatic disease; AND
 - D) Patient has tumor mutational burden-high (TMB-H) disease; AND
 - E) Patient has progressed following prior treatment; AND
 - F) Patient has no satisfactory alternative treatment options; AND
 - G) The medication is used in combination with Yervoy (ipilimumab intravenous infusion); AND
 - H) The medication is prescribed by or in consultation with an oncologist.
- 15. Cervical Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 18 years of age; AND

- B) Patient has programmed death ligand-1 (PD-L1) positive disease (combined positive score [CPS] ≥ 1); AND
- C) The medication is used as second-line or subsequent therapy; AND
- D) The medication is prescribed by or in consultation with an oncologist.

16. Diffuse High-Grade Gliomas. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is < 18 years of age; AND
- B) Patient has hypermutant tumor diffuse high-grade glioma; AND
- C) Patient meets ONE of the following (i or ii):
 - i. The medication is used for adjuvant treatment; OR
 - ii. The medication is used for recurrent or progressive disease; AND
- D) The medication is prescribed by or in consultation with an oncologist.

17. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has tried at least one prior systemic therapy; AND
Note: Examples are carboplatin, paclitaxel, docetaxel, cisplatin, doxorubicin, topotecan, ifosfamide, everolimus/letrozole.
- C) Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease; AND
- D) The medication is prescribed by or in consultation with an oncologist.

18. Extranodal NK/T-Cell Lymphomas. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has received an asparaginase-based chemotherapy regimen; AND
Note: Examples of asparaginase-based chemotherapy are dexamethasone, ifosfamide, pegaspargase, etoposide; and gemcitabine, pegaspargase, oxaliplatin.
- C) The medication is prescribed by or in consultation with an oncologist.

19. Gestational Trophoblastic Neoplasia. Approve for 1 year if the patient meets BOTH of the following (A and B):

- A) Patient meets one of the following (i or ii):
 - i. Patient has tried at least one previous chemotherapy regimen for recurrent or progressive disease; OR
Note: Examples of chemotherapy regimens contain etoposide, cisplatin/carboplatin, paclitaxel, bleomycin, ifosfamide, methotrexate.
 - ii. Patient has methotrexate-resistant high-risk disease; AND
- B) The medication is prescribed by or in consultation with an oncologist.

20. Kaposi Sarcoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient has classic disease; AND
- B) Patient has relapsed or refractory disease; AND
- C) The medication is used in combination with Yervoy (ipilimumab intravenous infusion); AND
- D) The medication is prescribed by or in consultation with an oncologist.

21. Merkel Cell Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is ≥ 18 years of age; AND
- B) Patient meets ONE of the following (i or ii):
 - i. Patient has disseminated Merkel cell carcinoma; OR
 - ii. The medication is used as neoadjuvant therapy; AND

- C) The medication is prescribed by or in consultation with an oncologist.
- 22. Neuroendocrine Tumors.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced or metastatic disease; AND
 - C) Patient meets one of the following (i or ii):
 - i. Patient has well differentiated, Grade 3 disease; OR
 - ii. Patient has poorly differentiated, large or small cell disease (other than lung); AND
 - D) The medication is used in combination with Yervoy (ipilimumab intravenous infusion); AND
 - E) The medication is prescribed by or in consultation with an oncologist.
- 23. Pediatric Hodgkin Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is < 18 years of age; AND
 - B) Patient has tried at least one prior systemic chemotherapy; AND
Note: Examples are AVPC (doxorubicin, vincristine, prednisone, cyclophosphamide), ABVE-PC (doxorubicin, bleomycin, vincristine, etoposide, prednisone, cyclophosphamide), OEPA (vincristine, etoposide, prednisone, doxorubicin).
 - C) If used for re-induction therapy, the medication is used in combination with Adcetris (brentuximab intravenous infusion); AND
 - D) The medication is prescribed by or in consultation with an oncologist.
- 24. Primary Mediastinal Large B-Cell Lymphoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient has relapsed or refractory disease; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. The medication is used as a single agent; OR
 - ii. The medication is used in combination with Adcetris (brentuximab intravenous infusion) after a partial response to therapy for relapsed or refractory disease; AND
 - C) The medication is prescribed by or in consultation with an oncologist.
- 25. Small Bowel Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced or metastatic disease; AND
 - C) The tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
 - D) The medication is prescribed by or in consultation with an oncologist.
- 26. Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- A) Patient is ≥ 18 years of age; AND
 - B) The medication is used as second-line or subsequent therapy; AND
 - C) The medication is prescribed by or in consultation with an oncologist.
- 27. Vulvar Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is ≥ 18 years of age; AND
 - B) Patient has human papilloma virus (HPV)-related disease; AND
 - C) Patient has tried at least one prior systemic therapy; AND
Note: Examples are cisplatin, carboplatin, fluorouracil, paclitaxel, bevacizumab.
 - D) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Opdivo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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