

Applicable Drugs: Opdivo (nivolumab),
Opdivo Qvantig (nivolumab and
hyaluronidase-nvhy, subcutaneous)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/19/2017

Date Last Reviewed / Revised: 4/16/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following FDA-approved diagnoses A through K AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indications(s)

A. Melanoma and meets one of the following criteria (1 OR 2):

1. Unresectable or metastatic melanoma and meets one of the following a) OR b):
 - a) Opdivo or Opdivo Qvantig will be used as a single agent.
 - b) Opdivo will be used in combination with Yervoy (ipilimumab).
2. Completely resected stage IIB, stage IIC, stage III, or stage IV melanoma
 - a) Opdivo or Opdivo Qvantig will be used for adjuvant treatment as a single agent
3. Minimum age requirement: 12 years old and older

B. Non-small cell lung cancer (NSCLC) and meets one of the following criteria 1, 2, OR 3:

1. Resectable (tumors ≥ 4 cm or node positive) NCSLC and meets criteria a OR b:
 - a) Opdivo or Opdivo Qvantig used for neoadjuvant treatment in combination with platinum-doublet chemotherapy.
 - b) Documentation that there are no known EGFR mutations or ALK rearrangements
 - (1) Opdivo or Opdivo Qvantig used for neoadjuvant treatment in combination with platinum-doublet chemotherapy, followed by single-agent Opdivo or Opdivo Qvantig for adjuvant treatment after surgery.
2. Metastatic NSCLC and meets one of the following criteria a) OR b):
 - a) Documentation the cancer expresses PD-L1 ($\geq 1\%$) as determined by an FDA-approved test.

- (1) Documentation that there are no EGFR or ALK genomic tumor aberrations.
 - (2) Request is for Opdivo.
 - (3) Opdivo will be used as first-line treatment in combination with Yervoy (ipilimumab).
- b) Documentation of progression on or after platinum-based chemotherapy.
 - (1) If EGFR or ALK genomic aberrations are present, then documentation of disease progression on FDA-approved therapy for these aberrations.
 - (2) Opdivo or Opdivo Qvantig will be used as a single agent.
3. Metastatic or recurrent NSCLC
 - a) Documentation that there are no EGFR or ALK genomic aberrations.
 - b) Request is for Opdivo.
 - c) Opdivo will be used as first-line treatment in combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy.
- C. Malignant pleural mesothelioma
 1. Documentation the cancer is unresectable.
 2. Request is for Opdivo.
 3. Opdivo will be used as a first line treatment in combination with ipilimumab Yervoy (ipilimumab).
- D. Renal cell carcinoma (RCC)
 1. Documentation of unresectable, metastatic, or relapsed RCC and one of the following criteria are met a), b), OR c):
 - a) Documentation of disease progression on or after prior anti-angiogenic therapy and Opdivo or Opdivo Qvantig will be used as a single agent.
 - b) Opdivo or Opdivo Qvantig will be used in combination with Cometriq (cabozantinib) for first-line treatment.
 - c) Documentation disease is intermediate or poor risk:
 - (1) Request is for Opdivo.
 - (2) Opdivo will be used in combination with Yervoy (ipilimumab) for first-line treatment.
- E. Classical Hodgkin lymphoma (cHL) and meets the following criteria 1 OR 2:

1. Documentation that disease has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and Adcetris (brentuximab vedotin) or 3 other lines of systemic chemotherapy that includes HSCT.
 - a) Request is for Opdivo.
 - b) Opdivo will be used as a single agent.
 - c) Minimum age requirement: 18 years old and older
 2. Documentation of previously untreated Stage III or IV disease
 - a) Request is for Opdivo.
 - b) Opdivo will be used in combination with doxorubicin, vinblastine, and dacarbazine (AVD)
 - c) Minimum age requirement: 12 years old and older
- F. Squamous cell carcinoma of the head and neck (SCCHN)
1. Documentation of metastatic or recurrent SCCHN.
 2. Documentation that disease has progressed on or after a platinum-based therapy.
 3. Opdivo or Opdivo Qvantig will be used as a single agent.
- G. Urothelial carcinoma (UC) and one of the following criteria are met (1, 2, OR 3):
1. The patient has undergone radical resection of urothelial carcinoma and is at high risk of recurrence.
 - a) Opdivo or Opdivo Qvantig will be used as adjuvant treatment as a single agent.
 2. Unresectable or metastatic UC
 - a) Opdivo or Opdivo Qvantig will be used first line in combination with cisplatin and gemcitabine for up to 6 cycles and then Opdivo or Opdivo Qvantig will be used as a single agent.
 3. Locally advanced or metastatic UC and meets criteria a OR b:
 - a) Documentation of disease progression during or following platinum-containing chemotherapy
 - (1) Opdivo or Opdivo Qvantig will be used as a single agent.
 - b) Documentation of disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
 - (1) Opdivo or Opdivo Qvantig will be used as a single agent.
- H. Colorectal cancer

1. Documentation of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and meets one of the following criteria a) OR b):
 - a) Documentation disease is unresectable or metastatic
 - (1) Opdivo will be used in combination with Yervoy (ipilimumab) for a maximum of 4 doses followed by Opdivo or Opdivo Qvantig as a single agent. Opdivo Qvantig is not approved for use with Yervoy.
 - b) Documentation disease is metastatic and has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan.
 - (1) Opdivo or Opdivo Qvantig will be used as a single agent.
 2. Minimum age requirement: 12 years old and older.
- I. Hepatocellular carcinoma
1. Documentation of unresectable or metastatic disease and meets one of the following criteria a) OR b)
 - a) Opdivo or Opdivo Qvantig will be used for first-line treatment
 - b) Documentation of previous treatment failure or intolerance to sorafenib
 2. Opdivo will be used in combination with Yervoy (ipilimumab) followed by Opdivo or Opdivo Qvantig monotherapy. Opdivo Qvantig is not indicated for use with Yervoy.
- J. Esophageal Cancer and criteria 1 OR 2 are met:
1. Completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease
 - a) Opdivo or Opdivo Qvantig will be used as adjuvant treatment.
 - b) Documentation of previous neoadjuvant chemoradiotherapy (CRT).
 - c) Opdivo or Opdivo Qvantig will be used as a single agent
 2. Unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) and one of the following criteria a) OR b) is met:
 - a) Documentation of previous treatment with fluoropyrimidine and platinum-based chemotherapy
 - (1) Opdivo or Opdivo Qvantig will be used as a single agent.
 - b) Tumor expresses programmed death ligand-1 (PDL1) greater than or equal to 1 and meets criteria (1) OR (2):

- (1) Opdivo or Opdivo Qvantig will be used as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy.
- (2) Opdivo will be used as first-line treatment in combination with Yervoy (ipilimumab). Opdivo Qvantig is not indicated for use with Yervoy.
- K. Gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma
 - 1. Documentation that cancer is advanced or metastatic.
 - 2. Documentation that tumor expresses programmed death ligand-1 (PDL1) greater than or equal to 1.
 - 3. Opdivo or Opdivo Qvantig will be used in combination with fluoropyrimidine- and platinum-containing chemotherapy.

Other uses with supportive evidence:

- L. Ampullary adenocarcinoma
- M. Anal carcinoma
- N. Appendiceal neoplasms and cancers
- O. Biliary tract cancers – cholangiocarcinoma
- P. Biliary tract cancers – gallbladder
- Q. Bladder cancer
- R. Bone cancer
- S. Central nervous system cancers
- T. Cervical Cancer
- U. Chronic lymphocytic leukemia
- V. Esophageal and esophagogastric cancers
- W. Gastric cancer
- X. Gestational trophoblastic neoplasia
- Y. Head and neck cancers
- Z. Hodgkin lymphoma
- AA. Kaposi sarcoma
- BB. Kidney Cancer
- CC. Melanoma
- DD. Merkel cell carcinoma
- EE. Neuroendocrine and adrenal tumors
- FF. Peritoneal mesothelioma
- GG. Pediatric aggressive mature B-cell lymphomas
- HH. Pediatric diffuse high-grade gliomas
- II. Pediatric Hodgkin lymphoma
- JJ. Rectal cancer

KK. Small bowel adenocarcinoma
LL. Small cell lung cancer
MM. Soft tissue sarcoma
NN. Squamous cell skin cancer
OO. T-cell lymphomas
PP. Thyroid carcinoma
QQ. Uterine cancer
RR. Vaginal cancer
SS. Vulvar cancer

- II. Minimum age requirement: 18 years old, unless noted under FDA approved diagnosis criteria.
- III. Treatment must be prescribed by or in consultation with an oncologist or a hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Opdivo Qvantig is NOT indicated for use in combination with Yervoy (ipilimumab).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Melanoma, unresectable or metastatic
 - Opdivo
 - Age 12 years and older and weighing 40 kg or more:
 - Monotherapy: 240 mg every 2 weeks, or 480 every 4 weeks
 - 1 mg/kg every 3 weeks with Yervoy (ipilimumab) for maximum 4 doses, then 240 mg every 2 weeks, or 480 every 4 weeks.
 - Pediatric patients aged 12 years and older and weighing less than 40kg:
 - Monotherapy: 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks

- 1 mg/kg every 3 weeks with Yervoy (ipilimumab) for a maximum of 4 doses, then 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks
 - Treatment duration: until disease progression or unacceptable toxicity
- Opdivo Qvantig (monotherapy only – not indicated in combination with ipilimumab)
 - Age 12 years old and older and weighing 40 kg or greater:
 - 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Pediatric patients age 12 years old and older and weigh 30 kg or greater but less than 40 kg:
 - 300 mg/5,000 units every 2 weeks or 600 mg/10,000 units every 4 weeks
 - Treatment duration: until disease progression or unacceptable toxicity
- Melanoma, adjuvant treatment:
 - Opdivo
 - Age 12 years old and older and weigh 40 kg or more:
 - 240 mg every 2 weeks or 480 mg every 4 weeks
 - Age 12 years old and older and weigh less than 40 kg:
 - 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks
 - Opdivo Qvantig
 - Age 12 years old and older and weighing 40 kg or greater:
 - 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Pediatric patients age 12 years old and older and weigh 30 kg or greater but less than 40 kg:
 - 300 mg/5,000 units every 2 weeks or 600 mg/10,000 units every 4 weeks
 - Maximum adjuvant treatment duration: 1 year
- Non-small cell lung cancer:
 - Neoadjuvant treatment for resectable NSCLC:
 - Opdivo
 - 360mg every 3 weeks with platinum-doublet chemotherapy every 3 weeks for 3-4 cycles
 - Opdivo Qvantig
 - 900 mg/15,000 units with platinum-doublet chemotherapy every 3 weeks for 3-4 cycles

- Adjuvant treatment
 - Opdivo
 - 480 mg every 4 weeks after surgery
 - Opdivo Qvantig
 - 1,200 mg/20,000 units every 4 weeks after surgery
 - Maximum treatment duration: 13 cycles
- Metastatic
 - Opdivo combination treatment
 - 360 mg every 3 weeks with Yervoy (ipilimumab) 1 mg/kg every 6 weeks +/- 2 cycles of chemotherapy
 - Maximum treatment duration: 2 years
 - Opdivo monotherapy
 - 240 mg every 2 weeks or 480 mg every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
 - Opdivo Qvantig monotherapy
 - 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
- Malignant pleural mesothelioma (Opdivo only):
 - Opdivo
 - 360 mg every 3 weeks with Yervoy (ipilimumab) 1 mg/kg every 6 weeks.
 - Maximum treatment duration: 2 years
- Renal Cell Carcinoma:
 - Opdivo
 - 240 mg every 2 weeks or 480 mg every 4 weeks (monotherapy or in combination with Cometriq (cabozantinib))
 - Maximum treatment duration for monotherapy: until disease progression or unacceptable toxicity
 - Maximum treatment duration in combination with Cometriq: 2 years for Opdivo.

- 3 mg/kg, followed by Yervoy (ipilimumab) 1 mg/kg on the same day, every 3 weeks for 4 doses, then Opdivo 240 mg every 2 weeks, or 480 every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
- Opdivo Qvantig
 - 600 mg/10,000 units every 2 weeks or 1,200 mg /20,000 units every 4 weeks (monotherapy or in combination with Cometriq (cabozantinib))
 - Maximum treatment duration for monotherapy: until disease progression or unacceptable toxicity
 - Maximum treatment duration in combination with Cometriq: 2 years for Opdivo Qvantig.
- Classical Hodgkin lymphoma (Opdivo Only)
 - Age 12 years old and older and weighing 40 kg or more:
 - Opdivo 240 mg in combination with doxorubicin, vinblastine, and dacarbazine (AVD) every 2 weeks for 6 cycles
 - Age 12 years old and older and weighing less than 40 kg:
 - Opdivo 3 mg/kg in combination with doxorubicin, vinblastine, and dacarbazine (AVD) every 2 weeks for 6 cycles
 - Monotherapy
 - Opdivo 240 mg every 2 weeks or 480 mg every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
- Squamous cell carcinoma of head and neck:
 - Opdivo
 - 240 mg every 2 weeks or 480 mg every 4 weeks
 - Opdivo Qvantig
 - 600 mg/10,000 units every 2 weeks or 1,200 mg /20,000 units every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
- Urothelial carcinoma:
 - Adjuvant and locally advanced or metastatic (single agent)
 - Opdivo
 - 240 mg every 2 weeks or 480 mg every 4 weeks
 - Opdivo Qvantig

- 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Maximum treatment duration (adjuvant): 1 year
 - Maximum treatment duration (locally advanced or metastatic): until disease progression or unacceptable toxicity
- First-line unresectable or metastatic
 - Opdivo
 - 360 mg every 3 weeks in combination with cisplatin and gemcitabine on the same day for up to 6 cycles, then 240 mg every 2 weeks or 480 mg every 4 weeks as a single agent
 - Opdivo Qvantig
 - 900 mg/15,000 units every 3 weeks with cisplatin and gemcitabine on the same day for up to 6 cycles, then 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Maximum treatment duration: up to 2 years
- Colorectal cancer, metastatic, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR):
 - Opdivo Monotherapy
 - Adult and pediatric patients 12 years old and older and weight 40 kg or greater: 240 mg every 2 weeks or 480 mg every 4 weeks.
 - Pediatric patients 12 years old and older and weigh less than 40 kg: 3 mg/kg every 2 weeks.
 - Maximum treatment duration: until disease progression or unacceptable toxicity
 - Opdivo Qvantig Monotherapy
 - Age 12 years old and older and weighing 40 kg or greater:
 - 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Pediatric patients age 12 years old and older and weigh 30 kg or greater but less than 40 kg:
 - 300 mg/5,000 units every 2 weeks or 600 mg/10,000 units every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
 - Opdivo in combination with Yervoy (ipilimumab)
 - Adult and pediatric patients 12 years old and older and 40 kg or greater:

- Opdivo 240 mg followed by Yervoy (ipilimumab) 1mg/kg on the same day every 3 weeks for a maximum of 4 doses followed by Opdivo 240 mg every 2 weeks or 480 mg every 4 weeks given as a single agent
 - Pediatric patients 12 years old and older weighing less than 40 kg:
 - Opdivo 3mg/kg followed by Yervoy (ipilimumab) 1mg/kg on the same day every 3 weeks for a maximum of 4 doses followed by Opdivo 3mg/kg every 2 weeks or 6 mg/kg every 4 weeks.
 - Maximum treatment duration: up to 2 years
- Hepatocellular carcinoma:
 - Opdivo 1 mg/kg followed by Yervoy (ipilimumab) 3 mg/kg on the same day every 3 weeks for 4 doses, followed by:
 - Opdivo 240 mg every 2 weeks or 480 mg every 4 weeks OR
 - Opdivo Qvantig 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Maximum treatment duration: until disease progression or unacceptable toxicity
- Esophageal or gastroesophageal junction cancer :
 - Opdivo
 - 240 mg every 2 weeks or 480 mg every 4 weeks
 - Maximum treatment duration (adjuvant treatment): 1 year
 - Maximum treatment duration (monotherapy): until disease progression or unacceptable toxicity
 - Opdivo Qvantig
 - 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks
 - Maximum treatment duration (adjuvant treatment): 1 year
 - Maximum treatment duration (monotherapy): until disease progression or unacceptable toxicity
 - Opdivo combination treatment
 - 240 mg every 2 weeks or 480 mg every 4 weeks in combination with chemotherapy regimen of fluoropyrimidine- and platinum-containing chemotherapy, OR
 - 3mg/kg every 2 weeks or 360mg every 3 weeks with ipilimumab 1mg/kg every 6 weeks
 - Maximum treatment duration: 2 years
 - Opdivo Qvantig combination treatment

- 600 mg/10,000 units every 2 weeks or 1,200 mg/20,000 units every 4 weeks in combination with chemotherapy regimen of fluoropyrimidine- and platinum-containing chemotherapy
 - Maximum treatment duration: 2 years
- Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma:
 - Opdivo
 - 240 mg every 2 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks
 - 360mg every 3 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks
 - Opdivo Qvantig
 - 600 mg/10,000 units every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks
 - 900 mg/15,000 units every 3 weeks with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks
 - Maximum treatment duration: up to 2 years

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

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13. Opdivo Qvantig. Prescribing information. Bristol-Myers Squibb Company. 2025. Accessed April 16, 2026. http://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.