

Miscellaneous J-Code Billing and Coding Information



Select a button in the menu below to learn more about OPDIVO Qvantig™

Indications



Important Safety Information



Recommended Dosing



Please see Section 2.3, Dose Modifications, in the Full Prescribing Information for additional dosing information.

Following the FDA approval of healthcare professional-administered therapies, providers may need to use temporary codes until unique drug codes are assigned. Please see the following page for additional information on coding and billing units.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions:

OPDIVO Qvantig is associated with the following Warnings and Precautions: severe and fatal immune-mediated adverse reactions including pneumonitis, colitis, hepatitis and hepatotoxicity, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, other immune-mediated adverse reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO Qvantig is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Indications

Advanced Renal Cell Carcinoma

OPDIVO Qvantig™, as monotherapy, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC) following treatment with intravenous nivolumab and ipilimumab combination therapy.

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.

OPDIVO Qvantig, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced RCC.

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with advanced RCC who have received prior anti-angiogenic therapy.

Unresectable or Metastatic Melanoma

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma.

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma following treatment with intravenous nivolumab and ipilimumab combination therapy.

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.

Adjuvant Treatment of Melanoma

OPDIVO Qvantig, as monotherapy, is indicated for the adjuvant treatment of adult patients with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.

Neoadjuvant Treatment of Resectable Non-Small Cell Lung Cancer

OPDIVO Qvantig, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer (NSCLC).

Neoadjuvant and Adjuvant Treatment of Resectable Non-Small Cell Lung Cancer

OPDIVO Qvantig, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by OPDIVO Qvantig as monotherapy in the adjuvant setting after surgical resection.

Metastatic Non-Small Cell Lung Cancer

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult 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 Qvantig.

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.

Squamous Cell Carcinoma of the Head and Neck

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

Urothelial Carcinoma

OPDIVO Qvantig, as monotherapy, is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.

OPDIVO Qvantig, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic UC.

Indications continued on page 3.

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment, they can also occur after discontinuation of OPDIVO Qvantig. Early identification and management are essential to ensure safe use of OPDIVO Qvantig.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Indications (cont'd)

Urothelial Carcinoma (cont'd)

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with locally advanced or metastatic UC who:

- have disease progression during or following platinum-containing chemotherapy.
- have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Microsatellite Instability-High or Mismatch Repair Deficient Metastatic Colorectal Cancer

OPDIVO Qvantig, as monotherapy or as monotherapy following treatment with intravenous nivolumab and ipilimumab combination therapy, is indicated for the treatment of adult patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of MSI-H or dMMR metastatic CRC.

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 confirmatory trials.

Hepatocellular Carcinoma

OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib and following treatment with intravenous nivolumab and ipilimumab.

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with HCC.

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.

Esophageal Cancer

OPDIVO Qvantig as monotherapy, is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT).

OPDIVO Qvantig, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC).

Limitations of Use: OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.

OPDIVO Qvantig as monotherapy, is indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy.

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

OPDIVO Qvantig, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Recommended Dosing

Monotherapy¹

Indications	OPDIVO Qvantig ^a recommended dosage	Duration of therapy ^b
Earlier stage and advanced disease across tumors ^c	600 mg nivolumab + 10,000 units hyaluronidase Q2W	Until disease progression (PD) or unacceptable toxicity or Until disease recurrence or unacceptable toxicity for up to 1 year
Maintenance following nivolumab + ipilimumab combination therapy ^d	1,200 mg nivolumab + 20,000 units hyaluronidase Q4W	

^aAdminister over 3-5 minutes. ^bDepending on the indication. ^cFor indications: Advanced RCC, unresectable or metastatic melanoma, metastatic NSCLC, SCCHN, locally advanced or metastatic UC, MSI-H or dMMR metastatic CRC, ESCC, adjuvant treatment of melanoma, adjuvant treatment of UC, and adjuvant treatment of resected esophageal or gastroesophageal junction cancer. ^dFor indications: Advanced RCC, unresectable or metastatic melanoma, MSI-H or dMMR metastatic CRC, and hepatocellular carcinoma.

QXW, every X weeks.

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Withhold or permanently discontinue OPDIVO Qvantig depending on severity (please see Section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO Qvantig interruption or discontinuation is required, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over for at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Recommended Dosing (cont'd)

Combination Therapy¹

Indications	OPDIVO Qvantig ^a recommended dosage		Duration of therapy
Advanced RCC	600 mg nivolumab + 10,000 units hyaluronidase Q2W	Combination with oral cabozantinib 40 mg QD without food	Until PD, unacceptable toxicity, or up to 2 years <i>Cabozantinib or chemotherapy: Until PD or unacceptable toxicity</i>
ESCC	1,200 mg nivolumab + 20,000 units hyaluronidase Q4W	Combination with fluoropyrimidine- and platinum-containing chemotherapy	
Neoadjuvant treatment of resectable NSCLC	900 mg nivolumab + 15,000 units hyaluronidase Q3W	Combination with platinum-doublet chemotherapy on the same day Q3W	In combination with platinum-doublet chemotherapy for 3 cycles
Neoadjuvant and adjuvant treatment of resectable NSCLC	Neoadjuvant: 900 mg nivolumab + 15,000 units hyaluronidase	Neoadjuvant: Combination with platinum-doublet chemotherapy on the same day Q3W	Neoadjuvant: Until PD or unacceptable toxicity, for up to 4 cycles
	Adjuvant: 1,200 mg nivolumab + 20,000 units hyaluronidase	Adjuvant: Following neoadjuvant therapy and surgery, administer as a single agent Q4W	Adjuvant: Until PD, recurrence, or unacceptable toxicity, for up to 13 cycles (up to 1 year)
First-line unresectable or metastatic urothelial carcinoma	900 mg nivolumab + 15,000 units hyaluronidase Q3W then 600 mg nivolumab + 10,000 units hyaluronidase Q2W or 1,200 mg nivolumab + 20,000 units hyaluronidase Q4W	Combination with cisplatin and gemcitabine on the same day (up to 6 cycles) Q3W then monotherapy	Up to 6 cycles of combination therapy then administer as a single agent until PD, unacceptable toxicity, or up to 2 years from first dose
Gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma	600 mg nivolumab + 10,000 units hyaluronidase Q2W or 900 mg nivolumab + 15,000 units hyaluronidase Q3W	Combination with fluoropyrimidine- and platinum-containing chemotherapy	Until PD, unacceptable toxicity, or up to 2 years <i>Chemotherapy: Until disease progression or unacceptable toxicity</i>

^aAdminister over 3-5 minutes.

QD, once daily; QXW, every X weeks.

SELECT IMPORTANT SAFETY INFORMATION

Immune-mediated Pneumonitis

OPDIVO Qvantig can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 2.8% (7/247) of patients receiving OPDIVO Qvantig, including Grade 3 (0.8%) and Grade 2 (2.0%) adverse reactions.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Miscellaneous J-Code Billing and Coding Information

Codes

Following FDA approval of new physician-administered therapies, physician providers may need to use temporary codes until unique drug codes are assigned.

Not Otherwise Classified (NOC) HCPCS Codes ²		Billing Units
J3590	Unclassified biologics	1 billing unit Payers may require the number of units to be “1” regardless of amount administered with an unspecified HCPCS code, but this can vary from payer to payer.
J9999	Not otherwise classified anti-neoplastic drugs	
J3490	Unclassified drugs	
C9399	Unclassified drugs or biologics	

When submitting an NOC claim using HCPCS codes listed above, include the following information in Box 19 of the 1500 Form:

- The drug name
- Method of administration
- Basis of measurement
- Total dosage and strength
- 11-digit NDC

Note that some payers may have character limits in Box 19, which may require abbreviations of the information included.

Depending on payer preferences for billing and coding, the required miscellaneous J-code and billing unit conversion for claim submission may vary. Therefore, the provider should confirm preference with the payer prior to submitting.

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

HCPCS, Healthcare Common Procedure Coding System.

SELECT IMPORTANT SAFETY INFORMATION

Immune-Mediated Colitis

OPDIVO Qvantig can cause immune-mediated colitis. A common symptom included in the definition of colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid- refractory immune-mediated colitis. In cases of corticosteroid- refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 2.8% (7/247) of patients receiving OPDIVO Qvantig, including Grade 3 (0.4%) and Grade 2 (2.4%) adverse reactions.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Miscellaneous J-Code Billing and Coding Information



Codes (cont'd)

NDC ¹	How Supplied ¹
11-digit NDC: 00003-6120-01	600 mg nivolumab and 10,000 units hyaluronidase per 5 mL (120 mg/2,000 units per mL) solution in a single-dose vial

The red zero converts the 10-digit NDC to the 11-digit NDC. Payer requirements regarding the use of NDCs may vary. Electronic data exchange generally requires use of the 11-digit NDC.

CPT [®] Code ³	
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

The information contained herein is not intended to provide specific coding and reimbursement advice for any specific patient or situation. You should check with your coding specialist to ensure appropriate submissions.

The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and the patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

For more information around billing and coding for OPDIVO Qvantig, please contact the payer or [BMS Access Support[®]](#).

CPT, Current Procedural Terminology; NDC, National Drug Code.
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SELECT IMPORTANT SAFETY INFORMATION

Immune-Mediated Hepatitis and Hepatotoxicity

OPDIVO Qvantig can cause immune-mediated hepatitis.

Immune-mediated hepatitis occurred in 2.4% (6/247) of patients receiving OPDIVO Qvantig, including Grade 3 (1.6%), and Grade 2 (0.8%) adverse reactions. Intravenous nivolumab in combination with cabozantinib can cause hepatic toxicity with higher frequencies of Grade 3 and 4 ALT and AST elevations compared to intravenous nivolumab alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are administered as single agents. With the combination of intravenous nivolumab and cabozantinib, Grades 3 and 4 increased ALT or AST were seen in 11% (35/320) of patients.

Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.



Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment, they can also occur after discontinuation of OPDIVO Qvantig. Early identification and management are essential to ensure safe use of OPDIVO Qvantig. Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue OPDIVO Qvantig depending on severity (please see Section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO Qvantig interruption or discontinuation is required, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over for at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Immune-Mediated Pneumonitis

OPDIVO Qvantig can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 2.8% (7/247) of patients receiving OPDIVO Qvantig, including Grade 3 (0.8%) and Grade 2 (2.0%) adverse reactions.

Immune-Mediated Colitis

OPDIVO Qvantig can cause immune-mediated colitis. A common symptom included in the definition of colitis was diarrhea. Cytomegalovirus (CMV) infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 2.8% (7/247) of patients receiving OPDIVO Qvantig, including Grade 3 (0.4%) and Grade 2 (2.4%) adverse reactions.

Immune-Mediated Hepatitis and Hepatotoxicity

OPDIVO Qvantig can cause immune-mediated hepatitis.

Immune-mediated hepatitis occurred in 2.4% (6/247) of patients receiving OPDIVO Qvantig, including Grade 3 (1.6%), and Grade 2 (0.8%) adverse reactions. Intravenous nivolumab in combination with cabozantinib can cause hepatic toxicity with higher frequencies of Grade 3 and 4 ALT and AST elevations compared to intravenous nivolumab alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are administered as single agents. With the combination of intravenous nivolumab and cabozantinib, Grades 3 and 4 increased ALT or AST were seen in 11% (35/320) of patients.

Immune-Mediated Endocrinopathies

OPDIVO Qvantig can cause primary or secondary adrenal insufficiency, immune-mediated hypophysitis, immune-mediated thyroid disorders, and Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Withhold OPDIVO Qvantig depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism; initiate hormone replacement as clinically indicated. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism; initiate hormone replacement or medical management as clinically indicated.

Monitor patients for hyperglycemia or other signs and symptoms of diabetes; initiate treatment with insulin as clinically indicated.

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Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Adrenal insufficiency occurred in 2% (5/247) of patients receiving OPDIVO Qvantig, including Grade 3 (0.8%) and Grade 2 (1.2%) adverse reactions. Adrenal insufficiency occurred in 4.7% (15/320) of patients with RCC who received intravenous nivolumab with cabozantinib, including Grade 3 (2.2%) and Grade 2 (1.9%) adverse reactions. Hypophysitis occurred in 0.6% (12/1994) of patients treated with single agent intravenous nivolumab, including Grade 3 (0.2%) and Grade 2 (0.3%). Thyroiditis occurred in 0.4% (1/247) of patients receiving OPDIVO Qvantig, including a Grade 1 (0.4%) adverse reaction.

Hyperthyroidism occurred in 0.8% (2/247) of patients receiving OPDIVO Qvantig, including Grade 2 (0.4%) adverse reactions. Hypothyroidism occurred in 9% (23/247) of patients receiving OPDIVO Qvantig, including Grade 2 (5.7%) adverse reactions.

Grade 3 diabetes occurred in 0.4% (1/247) of patients receiving OPDIVO Qvantig.

Immune-Mediated Nephritis with Renal Dysfunction

OPDIVO Qvantig can cause immune-mediated nephritis.

Grade 2 immune-mediated nephritis and renal dysfunction occurred in 1.2% (3/247) of patients receiving OPDIVO Qvantig.

Immune-Mediated Dermatologic Adverse Reactions

OPDIVO Qvantig can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens- Johnson Syndrome, toxic epidermal necrolysis (TEN), and DRESS (drug rash with eosinophilia and systemic symptoms), has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue OPDIVO Qvantig depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

Immune-mediated rash occurred in 7% (17/247) of patients, including Grade 3 (0.8%) and Grade 2 (2.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received OPDIVO Qvantig or intravenous nivolumab as single agent or in combination with chemotherapy or immunotherapy, or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions: *cardiac/vascular*: myocarditis, pericarditis, vasculitis; *nervous system*: meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *ocular*: uveitis, iritis, and other ocular inflammatory toxicities can occur; *gastrointestinal*: pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis; *musculoskeletal and connective tissue*: myositis/polymyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica; *endocrine*: hypoparathyroidism; *other (hematologic/immune)*: hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis (HLH), systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Some ocular IMAR cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

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Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with OPDIVO Qvantig. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between OPDIVO Qvantig and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with OPDIVO Qvantig prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and data from animal studies, OPDIVO Qvantig can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of nivolumab to cynomolgus monkeys from the onset of organogenesis through delivery resulted in increased abortion and premature infant death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO Qvantig and for 5 months after the last dose.

Increased Mortality in Patients with Multiple Myeloma when Nivolumab Is Added to a Thalidomide Analogue and Dexamethasone

In randomized clinical trials in patients with multiple myeloma, the addition of a PD-1 blocking antibody, including intravenous nivolumab, to a thalidomide analogue plus dexamethasone, a use for which no PD-1 or PD-L1 blocking antibody is indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Lactation

There are no data on the presence of nivolumab or hyaluronidase in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment and for 5 months after the last dose of OPDIVO Qvantig.

Serious Adverse Reactions

In Checkmate 67T, serious adverse reactions occurred in 28% of patients who received OPDIVO Qvantig (n=247). Serious adverse reactions in >1% of patients included pleural effusion (1.6%), pneumonitis (1.6%), hyperglycemia (1.2%), hyperkalemia (1.2%), hemorrhage (1.2%) and diarrhea (1.2%). Fatal adverse reactions occurred in 3 patients (1.2%) who received OPDIVO Qvantig and included myocarditis, myositis, and colitis complications. In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving intravenous nivolumab (n=268). Grade 3 and 4 adverse reactions occurred in 42% of patients receiving intravenous nivolumab. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving intravenous nivolumab were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving intravenous nivolumab (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving intravenous nivolumab. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving intravenous nivolumab were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). In Checkmate 067, the most frequent (≥10%) serious adverse reactions in the intravenous nivolumab arm (n=313) were diarrhea (2.2%), colitis (1.9%), and pyrexia (1.0%). In Checkmate 067, serious adverse reactions (74% and 44%), adverse reactions leading to permanent discontinuation (47% and 18%) or to dosing delays (58% and 36%), and Grade 3 or 4 adverse reactions (72% and 51%) all occurred more frequently in the intravenous nivolumab plus intravenous ipilimumab arm (n=313) relative to the intravenous nivolumab arm (n=313). The most frequent (≥10%) serious adverse reactions in the intravenous nivolumab plus intravenous ipilimumab arm and the intravenous nivolumab arm, respectively, were diarrhea (13% and 2.2%), colitis (10% and 1.9%), and pyrexia (10% and 1.0%).

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Please see [Important Safety Information](#) on pages 8-13 and [US Full Prescribing Information](#) for OPDIVO Qvantig.

Important Safety Information (cont'd)



In Checkmate 816, serious adverse reactions occurred in 30% of patients (n=176) who were treated with intravenous nivolumab in combination with platinum-doublet chemotherapy. Serious adverse reactions in >2% included pneumonia and vomiting. No fatal adverse reactions occurred in patients who received intravenous nivolumab in combination with platinum-doublet chemotherapy. In Checkmate 77T, serious adverse reactions occurred in 21% of patients who received intravenous nivolumab in combination with platinum-doublet chemotherapy as neoadjuvant treatment (n=228). The most frequent (≥2%) serious adverse reactions was pneumonia. Fatal adverse reactions occurred in 2.2% of patients, due to cerebrovascular accident, COVID-19 infection, hemoptysis, pneumonia, and pneumonitis (0.4% each). In the adjuvant phase of Checkmate 77T, 22% of patients experienced serious adverse reactions (n=142). The most frequent serious adverse reaction was pneumonitis/ILD (2.8%). One fatal adverse reaction due to COVID-19 occurred. In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving intravenous nivolumab (n=418). The most frequent serious adverse reactions reported in ≥2% of patients receiving intravenous nivolumab were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 057, fatal adverse reactions occurred; these included events of infection (7 patients, including one case of *Pneumocystis jirovecii* pneumonia), pulmonary embolism (4 patients), and limbic encephalitis (1 patient). In Checkmate 214, serious adverse reactions occurred in 59% of patients receiving intravenous nivolumab plus intravenous ipilimumab (n=547). The most frequent serious adverse reactions reported in ≥2% of patients were diarrhea, pyrexia, pneumonia, pneumonitis, hypophysitis, acute kidney injury, dyspnea, adrenal insufficiency, and colitis. In Checkmate 9ER, serious adverse reactions occurred in 48% of patients receiving intravenous nivolumab and cabozantinib (n=320). The most frequent serious adverse reactions reported in ≥2% of patients were diarrhea, pneumonia, pneumonitis, pulmonary embolism, urinary tract infection, and hyponatremia. Fatal intestinal perforations occurred in 3 (0.9%) patients.

In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving intravenous nivolumab (n=406). The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving intravenous nivolumab (n=236). The most frequent serious adverse reactions reported in ≥2% of patients receiving intravenous nivolumab were pneumonia, dyspnea, respiratory failure, respiratory tract infection, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving intravenous nivolumab (n=270). The most frequent serious adverse reactions reported in ≥2% of patients receiving intravenous nivolumab were urinary tract infection, sepsis, diarrhea, small intestine obstruction, and general physical health deterioration. In Checkmate 274, serious adverse reactions occurred in 30% of patients receiving intravenous nivolumab (n=351). The most frequent serious adverse reaction reported in ≥2% of patients receiving intravenous nivolumab was urinary tract infection. Fatal adverse reactions occurred in 1% of patients; these included events of pneumonitis (0.6%). In Checkmate 901, serious adverse reactions occurred in 48% of patients receiving intravenous nivolumab in combination with chemotherapy. The most frequent serious adverse reactions reported in ≥2% of patients who received intravenous nivolumab with chemotherapy were urinary tract infection (4.9%), acute kidney injury (4.3%), anemia (3%), pulmonary embolism (2.6%), sepsis (2.3%), and platelet count decreased (2.3%). Fatal adverse reactions occurred in 3.6% of patients who received intravenous nivolumab in combination with chemotherapy; these included sepsis (1%). In Checkmate 142 in MSI-H/dMMR mCRC patients receiving intravenous nivolumab with intravenous ipilimumab (n=119), serious adverse reactions occurred in 47% of patients. The most frequent serious adverse reactions reported in ≥2% of patients were colitis/diarrhea, hepatic events, abdominal pain, acute kidney injury, pyrexia, and dehydration. In Checkmate 040, serious adverse reactions occurred in 59% of patients receiving intravenous nivolumab with intravenous ipilimumab (n=49). Serious adverse reactions reported in ≥4% of patients were pyrexia, diarrhea, anemia, increased AST, adrenal insufficiency, ascites, esophageal varices hemorrhage, hyponatremia, increased blood bilirubin, and pneumonitis. In Checkmate 238, serious adverse reactions occurred in 18% of patients receiving intravenous nivolumab (n=452). Grade 3 or 4 adverse reactions occurred in 25% of intravenous nivolumab-treated patients (n=452). The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of intravenous nivolumab-treated patients were diarrhea and increased lipase and amylase. In Attraction-3, serious adverse reactions occurred in 38% of patients receiving intravenous nivolumab (n=209). Serious adverse reactions reported in ≥2% of patients who received intravenous nivolumab were pneumonia, esophageal fistula, interstitial lung disease, and pyrexia. The following fatal adverse reactions occurred in patients who received intravenous nivolumab: interstitial lung disease or pneumonitis (1.4%), pneumonia (1.0%), septic shock (0.5%), esophageal fistula (0.5%), gastrointestinal hemorrhage (0.5%), pulmonary embolism (0.5%), and sudden death (0.5%). In Checkmate 577, serious adverse reactions occurred in 33% of patients receiving intravenous nivolumab (n=532). A serious adverse reaction reported in ≥2% of patients who received intravenous nivolumab was pneumonitis. A fatal reaction of myocardial infarction occurred in one patient who received intravenous nivolumab. In Checkmate 648, serious adverse reactions occurred in 62% of patients receiving intravenous nivolumab in combination with chemotherapy (n=310). The most frequent serious adverse reactions reported in ≥2% of patients who received intravenous nivolumab with chemotherapy were pneumonia (11%), dysphagia (7%), esophageal stenosis (2.9%), acute kidney injury (2.9%), and pyrexia (2.3%). Fatal adverse reactions occurred in 5 (1.6%) patients who received OPDIVO in combination with chemotherapy; these included pneumonitis, pneumatosis intestinalis, pneumonia,

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Important Safety Information (cont'd)



and acute kidney injury. In Checkmate 648, serious adverse reactions occurred in 69% of patients receiving intravenous nivolumab in combination with intravenous ipilimumab (n=322). The most frequent serious adverse reactions reported in $\geq 2\%$ who received intravenous nivolumab in combination with intravenous ipilimumab were pneumonia (10%), pyrexia (4.3%), pneumonitis (4.0%), aspiration pneumonia (3.7%), dysphagia (3.7%), hepatic function abnormal (2.8%), decreased appetite (2.8%), adrenal insufficiency (2.5%), and dehydration (2.5%). Fatal adverse reactions occurred in 5 (1.6%) patients who received intravenous nivolumab in combination with intravenous ipilimumab; these included pneumonitis, interstitial lung disease, pulmonary embolism, and acute respiratory distress syndrome. In Checkmate 649, serious adverse reactions occurred in 52% of patients treated with intravenous nivolumab in combination with chemotherapy (n=782). The most frequent serious adverse reactions reported in $\geq 2\%$ of patients treated with intravenous nivolumab in combination with chemotherapy were vomiting (3.7%), pneumonia (3.6%), anemia, (3.6%), pyrexia (2.8%), diarrhea (2.7%), febrile neutropenia (2.6%), and pneumonitis (2.4%). Fatal adverse reactions occurred in 16 (2.0%) patients who were treated with intravenous nivolumab in combination with chemotherapy; these included pneumonitis (4 patients), febrile neutropenia (2 patients), stroke (2 patients), gastrointestinal toxicity, intestinal mucositis, septic shock, pneumonia, infection, gastrointestinal bleeding, mesenteric vessel thrombosis, and disseminated intravascular coagulation. In Checkmate 76K, serious adverse reactions occurred in 18% of patients receiving intravenous nivolumab (n=524). Adverse reactions which resulted in permanent discontinuation of intravenous nivolumab in $>1\%$ of patients included arthralgia (1.7%), rash (1.7%), and diarrhea (1.1%). A fatal adverse reaction occurred in 1 (0.2%) patient (heart failure and acute kidney injury). The most frequent Grade 3-4 lab abnormalities reported in $\geq 1\%$ of intravenous nivolumab-treated patients were increased lipase (2.9%), increased AST (2.2%), increased ALT (2.1%), lymphopenia (1.1%), and decreased potassium (1.0%).

Common Adverse Reactions

In Checkmate 67T, the most common adverse reactions ($\geq 10\%$) in patients treated with OPDIVO Qvantig (n=247) were musculoskeletal pain (31%), fatigue (20%), pruritus (16%), rash (15%), hypothyroidism (12%), diarrhea (11%), cough (11%), and abdominal pain (10%). In Checkmate 037, the most common adverse reaction ($\geq 20\%$) reported with intravenous nivolumab (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions ($\geq 20\%$) reported with intravenous nivolumab (n=206) vs dacarbazine (n=205) were fatigue (49% vs 39%), musculoskeletal pain (32% vs 25%), rash (28% vs 12%), and pruritus (23% vs 12%). In Checkmate 067, the most common ($\geq 20\%$) adverse reactions in the intravenous nivolumab arm (n=313) were fatigue (59%), rash (40%), musculoskeletal pain (42%), diarrhea (36%), nausea (30%), cough (28%), pruritus (27%), upper respiratory tract infection (22%), decreased appetite (22%), headache (22%), constipation (21%), arthralgia (21%), and vomiting (20%). In Checkmate 067, the most common ($\geq 20\%$) adverse reactions in the intravenous nivolumab plus intravenous ipilimumab arm (n=313) were fatigue (62%), diarrhea (54%), rash (53%), nausea (44%), pyrexia (40%), pruritus (39%), musculoskeletal pain (32%), vomiting (31%), decreased appetite (29%), cough (27%), headache (26%), dyspnea (24%), upper respiratory tract infection (23%), arthralgia (21%), and increased transaminases (25%).

In Checkmate 816, the most common ($>20\%$) adverse reactions in the intravenous nivolumab plus chemotherapy arm (n=176) were nausea (38%), constipation (34%), fatigue (26%), decreased appetite (20%), and rash (20%). In Checkmate 77T, the most common adverse reactions (reported in $\geq 20\%$) in patients receiving intravenous nivolumab in combination with chemotherapy (n= 228) were anemia (39.5%), constipation (32.0%), nausea (28.9%), fatigue (28.1%), alopecia (25.9%), and cough (21.9%). In Checkmate 017 and 057, the most common adverse reactions ($\geq 20\%$) in patients receiving intravenous nivolumab (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 214, the most common adverse reactions ($\geq 20\%$) reported in patients treated with intravenous nivolumab plus intravenous ipilimumab (n=547) were fatigue (58%), rash (39%), diarrhea (38%), musculoskeletal pain (37%), pruritus (33%), nausea (30%), cough (28%), pyrexia (25%), arthralgia (23%), decreased appetite (21%), dyspnea (20%), and vomiting (20%). In Checkmate 9ER, the most common adverse reactions ($\geq 20\%$) in patients receiving intravenous nivolumab and cabozantinib (n=320) were diarrhea (64%), fatigue (51%), hepatotoxicity (44%), palmar-plantar erythrodysesthesia syndrome (40%), stomatitis (37%), rash (36%), hypertension (36%), hypothyroidism (34%), musculoskeletal pain (33%), decreased appetite (28%), nausea (27%), dysgeusia (24%), abdominal pain (22%), cough (20%) and upper respiratory tract infection (20%). In Checkmate 025, the most common adverse reactions ($\geq 20\%$) reported in patients receiving intravenous nivolumab (n=406) vs everolimus (n=397) were fatigue (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 141, the most common adverse reactions ($\geq 10\%$) in patients receiving intravenous nivolumab (n=236) were cough (14%) and dyspnea (14%) at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions ($\geq 20\%$) reported in patients receiving intravenous nivolumab (n=270) were fatigue (46%), musculoskeletal pain (30%), nausea (22%), and decreased appetite (22%). In Checkmate 274, the most common adverse reactions (20%) reported in patients receiving intravenous nivolumab (n=351) were rash (36%), fatigue

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(36%), diarrhea (30%), pruritus (30%), musculoskeletal pain (28%), and urinary tract infection (22%). In Checkmate 901, the most common adverse reactions (reported in $\geq 20\%$ of patients) were nausea (52%), fatigue (48%), musculoskeletal pain (33%), constipation (30%), decreased appetite (30%), rash (25%), vomiting (23%), and peripheral neuropathy (20%). In Checkmate 142 in MSI-H/dMMR mCRC patients receiving intravenous nivolumab as a single agent (n=74), the most common adverse reactions ($\geq 20\%$) were fatigue (54%), diarrhea (43%), abdominal pain (34%), nausea (34%), vomiting (28%), musculoskeletal pain (28%), cough (26%), pyrexia (24%), rash (23%), constipation (20%), and upper respiratory tract infection (20%). In Checkmate 142 in MSI-H/dMMR mCRC patients receiving intravenous nivolumab with intravenous ipilimumab (n=119), the most common adverse reactions ($\geq 20\%$) were fatigue (49%), diarrhea (45%), pyrexia (36%), musculoskeletal pain (36%), abdominal pain (30%), pruritus (28%), nausea (26%), rash (25%), decreased appetite (20%), and vomiting (20%). In Checkmate 040, the most common adverse reactions ($\geq 20\%$) in patients receiving intravenous nivolumab with intravenous ipilimumab (n=49), were rash (53%), pruritus (53%), musculoskeletal pain (41%), diarrhea (39%), cough (37%), decreased appetite (35%), fatigue (27%), pyrexia (27%), abdominal pain (22%), headache (22%), nausea (20%), dizziness (20%), hypothyroidism (20%), and weight decreased (20%). In Checkmate 238, the most common adverse reactions ($\geq 20\%$) reported in intravenous nivolumab-treated patients (n=452) vs ipilimumab-treated patients (n=453) were fatigue (57% vs 55%), diarrhea (37% vs 55%), rash (35% vs 47%), musculoskeletal pain (32% vs 27%), pruritus (28% vs 37%), headache (23% vs 31%), nausea (23% vs 28%), upper respiratory infection (22% vs 15%), and abdominal pain (21% vs 23%). The most common immune-mediated adverse reactions were rash (16%), diarrhea/colitis (6%), and hepatitis (3%). In Attraction-3, the most common adverse reactions ($\geq 20\%$) in intravenous nivolumab-treated patients (n=209) were rash (22%) and decreased appetite (21%). In Checkmate 577, the most common adverse reactions ($\geq 20\%$) in patients receiving intravenous nivolumab (n=532) were fatigue (34%), diarrhea (29%), nausea (23%), rash (21%), musculoskeletal pain (21%), and cough (20%). In Checkmate 648, the most common adverse reactions ($\geq 20\%$) in patients treated with intravenous nivolumab in combination with chemotherapy (n=310) were nausea (65%), decreased appetite (51%), fatigue (47%), constipation (44%), stomatitis (44%), fatigue (32%), diarrhea (29%), and vomiting (23%). In Checkmate 648, the most common adverse reactions reported in $\geq 20\%$ of patients treated with intravenous nivolumab in combination with intravenous ipilimumab were rash (31%), fatigue (28%), pyrexia (23%), nausea (22%), diarrhea (22%), fatigue (21%), and constipation (20%). In Checkmate 649, the most common adverse reactions ($\geq 20\%$) in patients treated with intravenous nivolumab in combination with chemotherapy (n=782) were peripheral neuropathy (53%), nausea (48%), fatigue (44%), diarrhea (39%), vomiting (31%), decreased appetite (29%), abdominal pain (27%), constipation (25%), and musculoskeletal pain (20%). In Checkmate 76K, the most common adverse reactions ($\geq 20\%$) reported with intravenous nivolumab (n=524) were fatigue (36%), musculoskeletal pain (30%), rash (28%), diarrhea (23%) and pruritus (20%).

Surgery Related Adverse Reactions

In Checkmate 77T, 5.3% (n=12) of the intravenous nivolumab-treated patients who received neoadjuvant treatment, did not receive surgery due to adverse reactions. The adverse reactions that led to cancellation of surgery in intravenous nivolumab-treated patients were cerebrovascular accident, pneumonia, and colitis/diarrhea (2 patients each) and acute coronary syndrome, myocarditis, hemoptysis, pneumonitis, COVID-19, and myositis (1 patient each).

Summary of Warnings and Precautions:

OPDIVO Qvantig is associated with the following Warnings and Precautions: severe and fatal immune-mediated adverse reactions including pneumonitis, colitis, hepatitis and hepatotoxicity, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, other immune-mediated adverse reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO Qvantig is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

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References

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