Bristol Myers Squibb®

Access Support®

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A digital guide to access and reimbursement for

OPDIVO® (nivolumab)

INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™

nivolumab + hyaluronidase-nvhy

SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500051 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

Introduction

This digital reference guide includes general reimbursement information, coding, indications, and dosing for:

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO® is an injection for intravenous use.

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

OPDIVO Qvantig™ is an injection for subcutaneous use.

Healthcare providers should code healthcare claims based upon the service that is rendered, the patient's medical record, the coding requirements of each health insurer, and the best coding practices. 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.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Introduction

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Adjuvant Treatment of Melanoma	**Adjuvant Treatment of Melanoma**
OPDIVO® OPDIVO® is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.	**OPDIVO Qvantig™** 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.
Unresectable or Metastatic Melanoma	**Unresectable or Metastatic Melanoma**
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, as a single agent or in combination with YERVOY®, is indicated for the treatment of adult and pediatric patients 12 years of age and older with unresectable or metastatic melanoma.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy, or as monotherapy following treatment with intravenous OPDIVO® and YERVOY® combination therapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® for the treatment of unresectable or metastatic melanoma.
Neoadjuvant Treatment of Resectable NSCLC	**Neoadjuvant Treatment of Resectable NSCLC**
OPDIVO® + Chemotherapy OPDIVO®, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC).	**OPDIVO Qvantig™ + Chemotherapy** OPDIVO Qvantig™, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC).

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Introduction

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Neoadjuvant and Adjuvant Treatment of Resectable NSCLC	**Neoadjuvant and Adjuvant Treatment of Resectable NSCLC**
OPDIVO® + Chemotherapy OPDIVO®, 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 single-agent OPDIVO® as adjuvant treatment after surgery.	**OPDIVO Qvantig™ + Chemotherapy** 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.
1L mNSCLC (PD-L1 ≥1%)	**OPDIVO Qvantig™ is not indicated for this use.**
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.	
1L Metastatic or Recurrent NSCLC	**OPDIVO Qvantig™ is not indicated for this use.**
OPDIVO® + YERVOY® and 2 Cycles of Chemotherapy OPDIVO®, in combination with YERVOY® and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations.	

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Introduction

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
2L mNSCLC	**2L mNSCLC**
OPDIVO® OPDIVO® 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®.	**OPDIVO Qvantig™** 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 YERVOY® for the treatment of metastatic NSCLC.
1L Unresectable Malignant Pleural Mesothelioma	
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM).	**OPDIVO Qvantig™ is not indicated for this use.**
1L Intermediate or Poor Risk Advanced RCC	**1L Intermediate or Poor Risk Advanced RCC**
OPDIVO® + YERVOY® OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC).	**OPDIVO Qvantig™** 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 OPDIVO® and YERVOY® combination therapy. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® for the treatment of renal cell carcinoma.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Introduction

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1L Advanced RCC	**1L Advanced RCC**
OPDIVO® + cabozantinib OPDIVO®, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).	**OPDIVO Qvantig™ + cabozantinib** OPDIVO Qvantig™, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
2L Advanced RCC	**2L Advanced RCC**
OPDIVO® OPDIVO®, as a single agent, is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy, is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.
2L Relapsed/Progressed Classical Hodgkin Lymphoma	**OPDIVO Qvantig™ is not indicated for this use.**
OPDIVO® OPDIVO® is indicated for the treatment of classical Hodgkin lymphoma (cHL) in adult patients that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin or after 3 or more lines of systemic therapy that includes autologous HSCT. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.	
2L Squamous Cell Carcinoma of the Head and Neck	**2L Squamous Cell Carcinoma of the Head and Neck**
OPDIVO® OPDIVO® 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.	**OPDIVO Qvantig™** 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.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Introduction

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Adjuvant Treatment of UC	**Adjuvant Treatment of UC**
OPDIVO® OPDIVO® 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™** 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.
1L Unresectable or Metastatic UC	**1L Unresectable or Metastatic UC**
OPDIVO® + Chemotherapy OPDIVO®, in combination with cisplatin and gemcitabine, is indicated as first-line treatment for adult patients with unresectable or metastatic urothelial carcinoma.	**OPDIVO Qvantig™ + Chemotherapy** OPDIVO Qvantig™, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
2L Locally Advanced/Metastatic UC	**2L Locally Advanced/Metastatic UC**
OPDIVO® OPDIVO® is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma 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.	**OPDIVO Qvantig™** 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.

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OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Introduction

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
MSI-H/dMMR Metastatic Colorectal Cancer	
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC).	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy or as monotherapy following treatment with intravenous OPDIVO® and YERVOY® combination therapy, is indicated for the treatment of adult patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® 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.
OPDIVO® OPDIVO®, as a single agent, is indicated for the treatment of adult and pediatric patients 12 years and older 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.	
Unresectable or Metastatic Hepatocellular Carcinoma	
OPDIVO® + YERVOY® OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC).	**OPDIVO Qvantig™** 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 OPDIVO® and YERVOY®. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® 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.
OPDIVO® + YERVOY® OPDIVO®, in combination with YERVOY®, is indicated for the treatment of adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib.	

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Introduction

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1L Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma	**1L Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma**
OPDIVO® + Chemotherapy OPDIVO®, 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 whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™ + Chemotherapy** 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 whose tumors express PD-L1 (≥1).
Adjuvant Treatment of Completely Resected Esophageal Cancer or Gastroesophageal Junction Cancer	**Adjuvant Treatment of Completely Resected Esophageal Cancer or Gastroesophageal Junction Cancer**
OPDIVO® OPDIVO® 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™** 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).
1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma	**1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma**
OPDIVO®, in combination with fluoropyrimidine- and platinum-containing chemotherapy OPDIVO®, 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) whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™, in combination with fluoropyrimidine- and platinum-containing chemotherapy** 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) whose tumors express PD-L1 (≥1). Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® (ipilimumab) for the treatment of patients with unresectable advanced or metastatic ESCC.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Introduction

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma	
OPDIVO®, in combination with YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™ is not indicated for this use.**
2L Unresectable Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma	**2L Unresectable Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma**
OPDIVO® OPDIVO® is indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.	**OPDIVO Qvantig™** 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.

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BMS Access Support®

At Bristol Myers Squibb, We Provide Support With Purpose

Patients are the reason behind what we do. BMS Access Support is dedicated to helping patients access their prescribed BMS medications. When patients are prescribed OPDIVO® (nivolumab), OPDIVO® + YERVOY® (ipilimumab), or OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) and enroll in BMS Access Support, they will have access to:

Coverage Assistance

BMS Access Support may offer benefits investigations, prior authorization assistance, and appeal process support.*

Financial Support

Eligible, commercially insured patients may pay as little as $0 per dose.†

For patients insured through a government program or who do not have insurance, BMS Access Support can provide information regarding independent charitable foundations.‡

Educational Resources

A library of office support resources provides information about patient access, payer policy details, product distribution, coding, billing, and reimbursement. Patients also have access to educational materials to help them understand their insurance coverage.

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

†Restrictions apply. Please click here for full Terms and Conditions, including complete eligibility requirements.

‡It is important to note that charitable foundations are independent from Bristol-Myers Squibb Company and have their own eligibility criteria and evaluation process. Bristol Myers Squibb cannot guarantee that a patient will receive assistance.

We're here for you.

Patient access support, reimbursement resources, and financial support options may be available through **BMS Access Support®**

- Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday - Friday
- Find resources and enrollment information at **www.BMSAccessSupport.com**
- **Schedule a meeting** with an Access & Reimbursement Manager via the BMS Access Support website

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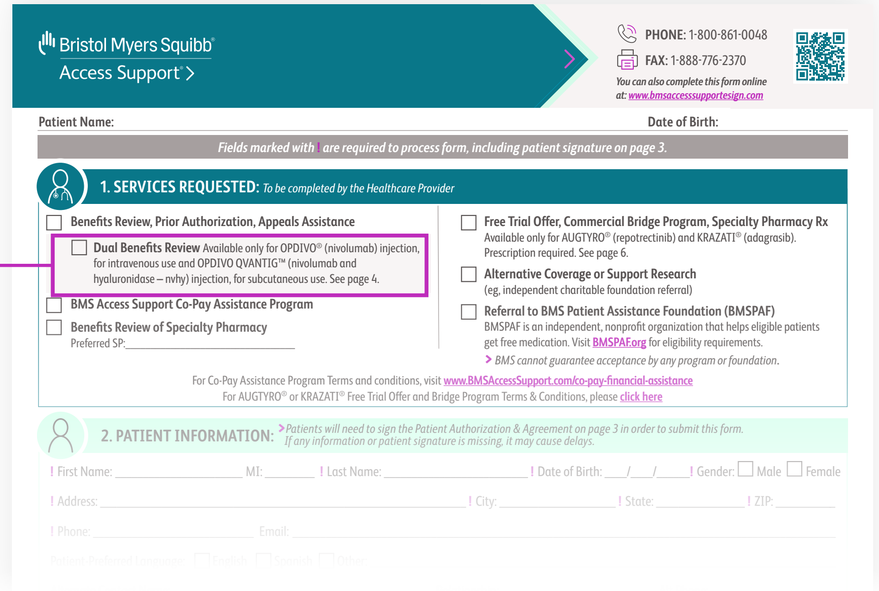
BMS Access Support®

BMS Access Support provides dual benefits reviews for OPDIVO® (nivolumab) and OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy)

Dual Benefits Reviews

When you select a Dual Benefits Review, BMS Access Support will conduct a review to determine the patient's insurance coverage for OPDIVO®, administered intravenously, in addition to a second review to determine insurance coverage for OPDIVO Qvantig™, administered subcutaneously.



Bristol Myers Squibb® Access Support®

PHONE: 1-800-861-0048
FAX: 1-888-776-2370
You can also complete this form online at: www.bmsaccesssupportesign.com

Patient Name: Date of Birth:

Fields marked with ! are required to process form, including patient signature on page 3.

1. SERVICES REQUESTED: *To be completed by the Healthcare Provider*

- ☐ **Benefits Review, Prior Authorization, Appeals Assistance**
  - ☐ **Dual Benefits Review** Available only for OPDIVO® (nivolumab) injection, for intravenous use and OPDIVO QVANTIG™ (nivolumab and hyaluronidase – nvhy) injection, for subcutaneous use. See page 4.
- ☐ **BMS Access Support Co-Pay Assistance Program**
- ☐ **Benefits Review of Specialty Pharmacy**
  Preferred SP:_____
- ☐ **Free Trial Offer, Commercial Bridge Program, Specialty Pharmacy Rx**
  Available only for AUGTYRO® (repotrectinib) and KRAZATI® (adagrasib). Prescription required. See page 6.
- ☐ **Alternative Coverage or Support Research**
  (eg, independent charitable foundation referral)
- ☐ **Referral to BMS Patient Assistance Foundation (BMSPAF)**
  BMSPAF is an independent, nonprofit organization that helps eligible patients get free medication. Visit BMSPAF.org for eligibility requirements.
  > *BMS cannot guarantee acceptance by any program or foundation.*

For Co-Pay Assistance Program Terms and conditions, visit www.BMSAccessSupport.com/co-pay-financial-assistance
For AUGTYRO® or KRAZATI® Free Trial Offer and Bridge Program Terms & Conditions, please click here

2. PATIENT INFORMATION: > *Patients will need to sign the Patient Authorization & Agreement on page 3 in order to submit this form. If any information or patient signature is missing, it may cause delays.*

! First Name: _____ MI: _____ ! Last Name: _____ ! Date of Birth: ___/___/_____ ! Gender: ☐ Male ☐ Female

! Address: _____ ! City: _____ ! State: _____ ! ZIP: _____

! Phone: _____ Email: _____

Preferred Preferred Language: ☐ English ☐ Spanish ☐ Other

Included in a Dual Benefits Review

After enrollment is complete, BMS Access Support will provide a summary of benefits that includes whether or not each medication is covered and if prior authorizations are required, in addition to other relevant information for HCP-administered products.

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

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General Reimbursement Information

MEDICARE DRUG REIMBURSEMENT FOR OPDIVO QVANTIG™

What is the Medicare reimbursement allowable for OPDIVO Qvantig™?

- The payment allowance limits for drugs and biologicals, such as OPDIVO Qvantig™, that are not included in the Average Sales Price (ASP) Medicare Part B Drug Pricing are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing[1]
- The payment allowance limit in the Medicare B Pricing File for OPDIVO Qvantig™ is typically WAC+3% for both hospital and physician offices. The billing unit is usually consistent with the unit of measure for that drug (grams, milligrams, units, etc)[1,2*†]
- Payment allowance limits are published each quarter in the Addendum B updates.[1] These are available at www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs[3]
- These prospective rate changes are updated annually, and pharmaceuticals receive no separate Medicare reimbursement when they are provided to hospital inpatients[3,4]

*While the statutory amount that Medicare will reimburse for a Part B Drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[1,5]

†See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

General Reimbursement Information

MEDICARE DRUG REIMBURSEMENT FOR OPDIVO®, OR OPDIVO® + YERVOY® (ipilimumab)

Physicians*

- The payment limit is 106% of average sales price (ASP),[1†] not including sequestration, and represents one billing unit of OPDIVO®, which is billed for each 1 mg
- The amount paid to physicians for OPDIVO® HCPCS code J9299 (and in the case of OPDIVO® + YERVOY®, YERVOY® HCPCS code J9228) is published at the beginning of each calendar quarter in "Payment Allowance Limits for Medicare Part B Drugs,"[1,6] which can be downloaded at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice
- Medicare Part B will pay physicians 80% of the allowed price for OPDIVO® HCPCS code J9299 (and in the case of OPDIVO® + YERVOY®, YERVOY® HCPCS code J9228); the patient is responsible for 20% co-insurance, which may be covered by secondary insurance (private supplemental coverage, Medicaid, etc)[6,7]

Hospital outpatient facilities*

Drugs paid separately under the hospital outpatient fee schedule are based on 106% of average sales price (ASP), not including sequestration, for one billing unit for the corresponding HCPCS code. This is 1 mg for OPDIVO® HCPCS code J9299 (and in the case of OPDIVO® + YERVOY®, 1 mg for YERVOY® HCPCS code J9228)[1,6†]

- The Payment Allowance Limits are published each quarter[1] at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice

Hospital inpatient settings

- Reimbursement in the inpatient setting is bundled into the Medicare Diagnosis Related Groups called MS-DRGs[3]
- These prospective rate changes are updated annually, and pharmaceuticals receive no separate Medicare reimbursement when they are provided to hospital inpatients[3,4]

*While the statutory amount that Medicare will reimburse for a Part B Drug in a physician office will remain at ASP +6%, sequestration has resulted in a reduction to the Medicare portion of the payment to Medicare providers. Essentially, all payments from Medicare carriers to the providers (including physician offices, hospitals, etc) will be reduced by 2%.[1,5]

†See the Centers for Medicare & Medicaid Services' (CMS) Internet Only Manual (IOM) Publication 100-04, Chapter 17-20.1.3.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

General Reimbursement Information

COMMERCIAL INSURANCE REIMBURSEMENT FOR OPDIVO®, OR OPDIVO® + YERVOY® (ipilimumab)

Physicians

- Drug reimbursement, like service reimbursement, is usually based on a fee schedule[8]
- The fee schedules are based on the ASP, as published by a credible source,[8,9] or an average costing methodology as determined by the payer, such as usual, customary, and reasonable (UC&R)[10]

Hospital outpatient facilities

- In this setting, reimbursement is most commonly based on percentage of charges[8]
- Alternatively, some hospitals use the same ASP methodology typically used by physician offices[8]
- Other methodologies include capitated model, cost minus submitted charges, or discount off submitted charges[8]

Hospital inpatient settings

- Inpatient rates are prospective, meaning they are predetermined per discharge[11]
- There are private payers that pay on a version of the DRGs[4]
- There are also payers that pay on a negotiated and fixed rate per day called a "per diem."[4] There are capitated rates for inpatients as well[4]
- New drugs may be carved out of per diems or capitated rates, if the hospital negotiates to do so[12]

References: **1.** Centers for Medicare & Medicaid Services. Part B drug payment limits overview. January 2025. Accessed January 24, 2025. https://www.cms.gov/files/document/part-b-drug-payment-limits-overview.pdf-0 **2.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Revision 12671. June 6, 2024. Accessed December 16, 2024. http://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf **3.** Centers for Medicare & Medicaid Services. FY 2025 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) Final Rule –- CMS-1808-F. August 1, 2024. Accessed February 12, 2025. https://www.cms.gov/newsroom/fact-sheets/fy-2025-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospital-prospective-0 **4.** AMCP Task Force on Drug Payment Methodologies. AMCP Guide to Pharmaceutical Payment Methods, Executive Edition. *J Manag Care Pharm*. 2007;13(8 suppl C):S1-S39. **5.** Centers for Medicare & Medicaid Services. CMS Medicare FFS Provider e-news. March 8, 2013. Accessed January 24, 2025. https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf **6.** American Medical Association. HCPCS Level II Expert 2025. American Medical Association; 2024. **7.** Centers for Medicare & Medicaid Services. Drug coverage under different parts of Medicare. March 2023. Accessed January 24, 2025. https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf **8.** Magellan Rx Management. Medical Pharmacy Trend Report 2024. Accessed January 24, 2025. https://issuu.com/primetherapeutics/docs/2024-medical-pharmacy-trend-report **9.** American Society of Clinical Oncology. Payment reform glossary. ASCO website. Accessed January 24, 2025. https://society.asco.org/sites/new-www.asco.org/files/content-files/blog-release/pdf/Payment-Reform-Glossary.pdf **10.** US Bureau of Labor Statistics. Definitions of health insurance terms. Accessed January 24, 2025. https://www.bls.gov/ebs/additional-resources/definition-of-health-insurance-terms.pdf **11.** Centers for Medicare & Medicaid Services. Acute inpatient PPS. Accessed January 24, 2025. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/acuteinpatientpps **12.** Academy of Managed Care Pharmacy. Managed care glossary. AMCP website. Accessed January 24, 2025. https://www.amcp.org/about/managed-care-pharmacy-101/managed-care-glossary

General Reimbursement Information

Use the following claim formats when OPDIVO®, OPDIVO® + YERVOY® (ipilimumab), or OPDIVO Qvantig™ is administered to patients on an outpatient basis and billed to health plans:

- Physician office: CMS-1500 (paper format) or ASC 837P (electronic format)
- Hospital outpatient: UB-04 (CMS-1450) [paper format] or ASC 837I (electronic format)
- **JW modifier** – Providers and suppliers are required to report the JW modifier on Part B drug claims for discarded drugs and biologicals. Also, providers and suppliers must document the amount of discarded drugs or biologicals in Medicare beneficiaries' medical records[1]
- **JZ modifier** – Starting no later than July 1, 2023, providers and suppliers are required to attest if there were no discarded amounts of drugs and biologicals[1]
- **TB modifier** – Starting Jan. 1, 2025, the TB modifier is to be used in place of the JG modifier by hospital outpatient departments to identify if the drug was obtained through 340B pricing.[2] Note that use of this modifier will not trigger any differentiated payment.

All the coding information presented is applicable to outpatient procedures only.

Sample Claim Forms

See sample claim forms for OPDIVO®, OPDIVO® and YERVOY®, and OPDIVO Qvantig™.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

NDC Codes

The NDC for OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

Storage Information[3]

Store under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light by storing in the original package until time of use. Do not freeze or shake.

How Supplied[3]

600 mg nivolumab and 10,000 units hyaluronidase/5 mL (120 mg nivolumab and 2,000 units hyaluronidase/mL) solution in a single-dose vial

0003-6120-01

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.

REFERENCES

NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms | Billing Conversion

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

HCPCS CODE EFFECTIVE JULY 1, 2025

The codes that may be appropriate when administering OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) appear in the tables below.

Recommended HCPCS Code[4]

HCPCS Code	Description	Billing Units
J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy	2 mg = 1 Billing Unit

Revenue Codes[5] (for Use in the Hospital Outpatient Setting)

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

Revenue Code	Description
0636	Drugs requiring detailed coding
0250	Pharmacy (general)
0331	Chemotherapy administered, injected

Recommended CPT Code*[6]

CPT Code	Description
96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic

5010 Transaction Coding

- For electronic transactions, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it.[7] This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter)[7]
- The example given below demonstrates NDC quantity reporting for 1 vial of OPDIVO Qvantig™. The actual amount of drug used can vary based on factors such as indication or patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format
  - » NDC qualifier=N4, Quantity qualifier=ML

Vial Size[3]	11-Digit NDC[3]	Sample of NDC 5010 Format
600 mg nivolumab and 10,000 units hyaluronidase/5 mL vial	00003-6120-01	N400003612001ML5

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.

REFERENCES

HCPCS, Healthcare Common Procedure Coding System; IV=intravenous; NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms | CMS 1500 Form | UB-04 Form | Billing Conversion

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
19	Some payers may require detailed information about the drug in Box 19.[7] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: OPDIVO QVANTIG (nivolumab and hyaluronidase-nvhy) Total dosage and strength: Specify total dosage given Method of administration: Subcutaneous Injection (SubQ or SC) 11-digit NDC[3]: 00003-6120-01 Note that some payers may have character limits in Box 19, which may require abbreviations of the information included.
24A	NDC information is required in the shaded area above the line on which a drug is reported in 24D. The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (ML) and the quantity administered.[7]	Example 1: N400003612001ML5
24D	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[7]	HCPCS code[4]: J9289 CPT code[6]: 96401 To record waste: It is required to enter the HCPCS code with a JW modifier (eg, J9289-JW) on the next line to record waste.[1] For no wastage: Enter the HCPCS code with a JZ modifier (eg, J9289-JZ) to attest that there were no discarded amounts.[1]
24G	Billing units are reported here.[7]	Billing units[4]: 1 billing unit per 2 mg of nivolumab, with hyaluronidase-nvhy Example 1[3,4]: 600 mg nivolumab + 10,000 units hyaluronidase injection of OPDIVO Qvantig: Enter 300 billing units. Example 2[3,4]: 900 mg nivolumab + 15,000 units hyaluronidase injection of OPDIVO Qvantig: Enter 450 billing units for the amount administered and, on a separate line, enter 150 billing units discarded using modifier JW in Item 24D for a total of 600 billing units.

Dosing scenarios without wastage[3,4]

1 vial administered (600 mg nivolumab + 10,000 units hyaluronidase)[3]

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) OPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1	N40003612001ML5												
	Date						11		J9289	JZ			300
2													
	Date						11		96401				1

2 vials administered (1,200 mg nivolumab + 20,000 units hyaluronidase)[3]

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) OPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1	N40003612001ML10												
	Date						11		J9289	JZ			600
2													
	Date						11		96401				1

Dosing scenario requiring wastage[3,4]

1.5 vials administered (900 mg nivolumab + 15,000 units hyaluronidase)[3]

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) OPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS
1	N40003612001ML7.5												
	Date						11		J9289				450
2	N40003612001ML2.5												
	Date						11		J9289	JW			150
3													
	Date						11		96401				1

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

CMS, Centers for Medicare and Medicaid Services;
HCPCS=Healthcare Common Procedure Coding System.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms | CMS 1500 Form | UB-04 Form | Billing Conversion

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
Field Locator (FL) 43	• Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[8] • Report quantity qualifier (ML) followed by quantity administered beginning in position 14.[8]	Example 1: N400003612001ML5
FL 44	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[8]	HCPCS code[4]: J9289 CPT code[6]: 96401 To record waste: It is required to enter the HCPCS code with a JW modifier (eg, J9289-JW) on the next line to record waste.[1] For no wastage: Enter the HCPCS code with a JZ modifier (eg, J9289-JZ) to attest that there were no discarded amounts.[1]
FL46	Billing units (service units) are reported here.[8]	Billing units[4]: 1 billing unit per 2 mg of nivolumab, with hyaluronidase-nvhy Example 1[3,4]: 600 mg nivolumab + 10,000 units hyaluronidase injection of OPDIVO Qvantig™: Enter 300 billing units. Example 2[3,4]: 900 mg nivolumab + 15,000 units hyaluronidase injection of OPDIVO Qvantig™: Enter 450 billing units for the amount administered and on a separate line, enter 150 billing units discarded using modifier JW in FL44 for a total of 600 billing units.
FL80	Some payers require detailed information about the drug in FL 80.[8] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: OPDIVO QVANTIG (nivolumab and hyaluronidase-nvhy) Total dosage and strength: Specify total dosage given Method of administration: Subcutaneous Injection (SubQ or SC) 11-digit NDC[3]: 00003-6120-01 Note that some payers may have character limits in FL 80, which may require abbreviations of the information included.

Dosing scenarios without wastage[3,4]

1 vial administered (600 mg nivolumab + 10,000 units hyaluronidase)[3]

	42 REV. CO.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	0636	N40003612001ML5	J9289-JZ	Date	300

2 vials administered (1,200 mg nivolumab + 20,000 units hyaluronidase)[3]

	42 REV. CO.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	0636	N40003612001ML10	J9289-JZ	Date	600

Dosing scenario requiring wastage[3,4]

1.5 vials administered (900 mg nivolumab + 15,000 units hyaluronidase)[3]

	42 REV. CO.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	0636	N40003612001ML7.5	J9289	Date	450
2	0636	N40003612001ML2.5	J9289-JW	Date	150

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

CMS, Centers for Medicare and Medicaid Services;
HCPCS=Healthcare Common Procedure Coding System.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Intravenous to Subcutaneous Billing Unit Conversion

Billing Unit Conversion for OPDIVO® and OPDIVO Qvantig™

OPDIVO® Recommended Dose[9]*	1 mg = 1 Billing Unit[10]
240 mg nivolumab	240 Billing Units
360 mg nivolumab	360 Billing Units
480 mg nivolumab	480 Billing Units

OPDIVO Qvantig™ Recommended Dose[3]*	2 mg = 1 Billing Unit[4]
600 mg nivolumab + 10,000 units hyaluronidase	 300 Billing Units
900 mg nivolumab + 15,000 units hyaluronidase	 450 Billing Units 150 Units JW Modifier†
1,200 mg nivolumab + 20,000 units hyaluronidase	 600 Billing Units

*Dosing regimen varies by indication.

†In the CMS 1500 Form (Item 24D) or UB-04 Form (Item FL-44), it is required to enter the HCPCS code with a JW modifier (eg, J9289-JW) on the next line to record waste. Alternatively, if no wastage, enter the HCPCS code with a JZ modifier (eg, J9289-JZ) to attest that there were no discarded amounts.[1,7,8]

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.

REFERENCES

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

NDC Codes

The NDCs for OPDIVO® (nivolumab), listed in the tables below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

Storage Information[9]

Store under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light by storing in the original package until time of use. Do not freeze or shake.

How Supplied[9]

40 mg/4 mL Single-dose vial	100 mg/10 mL Single-dose vial	120 mg/12 mL Single-dose vial	240 mg/24 mL Single-dose vial
0003-3772-11	0003-3774-12	0003-3756-14	0003-3734-13

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.

REFERENCES

NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

Recommended HCPCS Code[10]

HCPCS Code	Description	Billing Units
J9299	Injection, nivolumab, 1 mg	1 mg = 1 Billing Unit

Revenue Codes[5] (for Use in the Hospital Outpatient Setting)

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

Revenue Code	Description
0636	Drugs requiring detailed coding
0335	Chemotherapy administration, IV
0260	IV therapy

Recommended CPT Code*[6]

CPT Code	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

5010 Transaction Coding

- For electronic transactions, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it.[7] This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter)[7]
- The example given below demonstrates NDC quantity reporting for 1 vial of OPDIVO®. The actual amount of drug used can vary based on factors such as indication or patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format
  - » NDC qualifier=N4, Quantity qualifier=ML

Vial Size[9]	11-Digit NDC[9]	Sample of NDC 5010 Format
40 mg/4 mL vial	00003-3772-11	N400003377211ML4
100 mg/10 mL vial	00003-3774-12	N400003377412ML10
120 mg/12 mL vial	00003-3756-14	N400003375614ML12
240 mg/24 mL vial	00003-3734-13	N400003373413ML24

*CPT codes and descriptions only are ©2024 by American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

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.

REFERENCES

NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

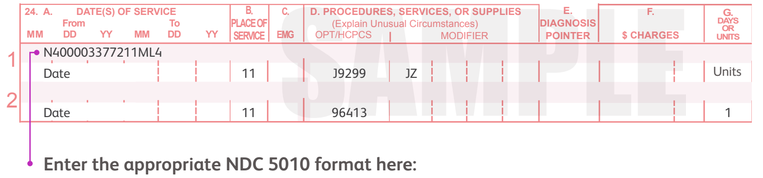
The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms — CMS 1500 Form | UB-04 Form

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
19	Some payers may require detailed information about the drug in Box 19.[7] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: OPDIVO® (nivolumab) Total dosage and strength: Specify total dosage given Method of administration: Intravenous Infusion (IV) 11-digit NDC[9]: Example 1: 00003-3772-11 Note that some payers may have character limits in Box 19, which may require abbreviations of the information included.
24A	NDC information is required in the red shaded area above the line on which a drug is reported in 24D. The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (ML) and the quantity administered.[7]	Example 1: N400003377211ML4 See sample claim form on this page for additional examples.
24D	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[7]	HCPCS code[10]: J9299 CPT code[6]: 96413 See sample claim form on this page for detailed instruction. In addition, it is required that you enter J9299-JW on next line to record waste. Alternatively, if no wastage, enter J9299-JZ to attest there were no discarded amounts.[1]
24G	Billing units are reported here[7]	For OPDIVO®, 1 mg = 1 Billing Unit[10]



Enter the appropriate NDC 5010 format here:

- N400003377211ML4
- N400003377412ML10
- N400003375614ML12
- N400003373413ML24

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY® (ipilimumab)

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms: CMS 1500 Form | UB-04 Form

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
Field Locator (FL) 42	• Enter the 4-digit revenue code for service provided in accordance with hospital billing policy.[8]	• For chemotherapy administration, revenue codes 0260 (IV therapy) or 0335 (radiology–therapeutic: chemotherapy–IV) could be used.[5] • CMS recommends using 0636 (drugs requiring detailed coding).[5,11]
FL 43	Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[8] Report quantity qualifier (ML) followed by quantity administered beginning in position 1.[8]	Example 1: N400003377211ML4 See sample claim form on this page for additional examples.
FL44	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[8]	HCPCS code[10]: J9299 CPT code[6]: 96413 To record waste: It is required to enter the HCPCS code with a JW modifier (eg, J9299-JW) on the next line to record waste.[1] For no wastage: Enter the HCPCS code with a JZ modifier (eg, J9299-JZ) to attest that there were no discarded amounts.[1] See sample claim form on this page for detailed instruction.
FL46	Billing units (service units) are reported here.[8]	For OPDIVO®, 1 mg = 1 Billing Unit[10]
FL80	Some payers require detailed information about the drug in FL 80.[8] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: OPDIVO (nivolumab) Total dosage and strength: Specify total dosage given Method of administration: Intravenous Infusion (IV) 11-digit NDC[9]: Example 1: 00003-3772-11 Note that some payers may have character limits in FL 80, which may require abbreviations of the information included.

42 REV. CO.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1 0636	N400003377211ML4	J9299-JZ	Date	Units

SAMPLE

Enter the appropriate NDC 5010 format here:

- N400003377211ML4
- N400003377412ML10
- N400003375614ML12
- N400003373413ML24

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY®

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms

YERVOY® (ipilimumab)
Injection for intravenous use 5 mg/mL

NDC Codes

The NDCs for YERVOY® (ipilimumab), listed in the tables below, are often necessary in addition to the appropriate J-code when filing a claim for reimbursement.

How Supplied[12]

One 200 mg /40 mL (5 mg/mL), single-dose vial
200-mg vial = 200 billable units

0003-2328-22

Storage Information[12]

Store under refrigeration at 2°C to 8°C (36°F to 46°F). Protect from light by storing in the original package until time of use. Do not freeze or shake.

One 50 mg /10 mL (5 mg/mL), single-dose vial
50-mg vial = 50 billable units

0003-2327-11

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.

REFERENCES

NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY®

OPDIVO QVANTIG™ OPDIVO® YERVOY®

YERVOY® (ipilimumab) Injection for intravenous use 5 mg/mL

The codes that may be appropriate when administering YERVOY® (ipilimumab) appear in the tables below.

Recommended HCPCS Code[10]

HCPCS Code	Description	Billing Units
J9228	Injection, ipilimumab, 1 mg	1 mg = 1 Billing Unit

Revenue Codes[5] (for Use in the Hospital Outpatient Setting)

Revenue codes categorize services in the hospital by revenue center. Medicare and most Medicaid and private payer claims must include revenue codes in field 42 of form UB-04 (CMS-1450).

Revenue Code	Description
0636	Drugs requiring detailed coding
0335	Chemotherapy administration, IV
0260	IV therapy

Recommended CPT Codes*[6]

CPT Code	Description
96417	Chemotherapy administration, IV infusion; each additional sequential infusion (different substance/drug), up to 1 hour†
96415	Chemotherapy administration, IV infusion; each additional hour‡

5010 Transaction Coding

- For electronic transactions, the 11-digit NDC is to be preceded by the qualifier N4 for payers that require it.[7] This is typically followed by the quantity qualifier, such as UN (units), F2 (international units), GR (gram), or ML (milliliter)[7]
- The example given below demonstrates NDC quantity reporting for 1 vial of YERVOY®. The actual amount of drug used can vary based on factors such as indication or patient weight. Currently, reporting NDC quantity varies from payer to payer, so the provider should consult each specific payer to determine the required format.
  - » NDC qualifier=N4, Quantity qualifier=ML

Vial Size[12]	11-Digit NDC[12]	Sample of NDC 5010 Format
50 mg/10 mL vial	00003-2327-11	N400003232711ML10
200 mg/40 mL vial	00003-2328-22	N400003232822ML40

*CPT codes and descriptions only are ©2024 by American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

†List separately in addition to code for primary procedure. Use 96417 in conjunction with 96413.

‡List separately in addition to code for primary procedure. Report 96415 for infusion intervals of greater than 30 minutes beyond 1-hour increments.

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.

REFERENCES

NDC, National Drug Code.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY®

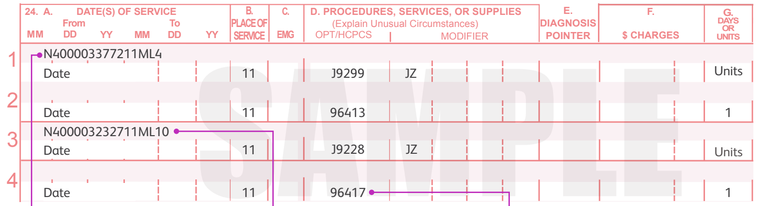
OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms — CMS 1500 Form | UB-04 Form

When YERVOY® is administered in combination with OPDIVO®, additional codes are required.

YERVOY® (ipilimumab)
Injection for intravenous use 5 mg/mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
19	Some payers may require detailed information about the drug in Box 19.[7] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: YERVOY® (ipilimumab) Total dosage and strength: Specify total dosage given Method of administration: Intravenous Infusion (IV) 11-digit NDC[12]: Example 1: 0003-2327-11 Note that some payers may have character limits in Box 19, which may require abbreviations of the information included.
24A	NDC information is required in the red shaded area above the line on which a drug is reported in 24D. The NDC is preceded by the qualifier N4 and followed by the quantity qualifier (ML) and the quantity administered.[7]	Example 1: N400003232711ML10 See sample claim form on this page for additional examples.
24D	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[7]	HCPCS code[10]: J9228 Use appropriate CPT code(s) for drug administration services.[6] See sample claim form on this page for detailed instruction. In addition, it is required that you enter J9228-JW on next line to record waste. Alternatively, if no wastage, enter J9228-JZ to attest there were no discarded amounts.[1]
24G	Billing units are reported here[7]	For YERVOY®, 1 mg = 1 Billing Unit[10]



Enter the appropriate NDC 5010 format for OPDIVO® here:

- N400003377211ML4
- N400003377412ML10
- N400003375614ML12
- N400003373413ML24

Enter the appropriate NDC 5010 format for YERVOY® here:

- N400003232711ML10
- N400003232822ML40

Enter the appropriate CPT code for YERVOY® here:

- 96417
- 96415

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY®

OPDIVO QVANTIG™ OPDIVO® YERVOY®

NDC & Storage | HCPCS, Revenue, CPT, 5010 | Sample Claim Forms: CMS 1500 Form | UB-04 Form

When YERVOY® is administered in combination with OPDIVO®, additional codes are required.

YERVOY® (ipilimumab) Injection for intravenous use 5 mg/mL

ITEM NO.	REQUIRED INFORMATION	INFORMATION TO ENTER
Field Locator (FL) 42	• Enter the 4-digit revenue code for service provided in accordance with hospital billing policy.[8]	• For chemotherapy administration, revenue codes 0260 (IV therapy) or 0335 (radiology–therapeutic: chemotherapy–IV) could be used.[5] • CMS recommends using 0636 (drugs requiring detailed coding).[5,11]
FL 43	Enter the modifier "N4" followed by the 11-digit NDC in positions 01-13.[8] Report quantity qualifier (ML) followed by quantity administered beginning in position 1.[8]	Example 1: N400003232711ML10 See sample claim form on this page for additional examples.
FL44	Enter the appropriate HCPCS code and CPT code(s) for drug administration services.[8]	HCPCS code[10]: J9228 Use appropriate CPT code(s) for drug administration services.[6] To record waste: It is required to enter the HCPCS code with a JW modifier (eg, J9299-JW) on the next line to record waste.[1] For no wastage: Enter the HCPCS code with a JZ modifier (eg, J9299-JZ) to attest that there were no discarded amounts.[1] See sample claim form on this page for detailed instruction.
FL46	Billing units (service units) are reported here.[8]	For YERVOY®, 1 mg = 1 Billing Unit[10]
FL80	Some payers require detailed information about the drug in FL 80.[8] This may include: • Drug name • Total dosage and strength • Method of administration • 11-digit NDC	Drug name: YERVOY® (ipilimumab) Total dosage and strength: Specify total dosage given Method of administration: Intravenous Infusion (IV) 11-digit NDC[12]: Example 1: 0003-2327-11 Note that some payers may have character limits in FL 80, which may require abbreviations of the information included.

	42 REV. CO.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS
1	0636	N400003377211ML4	J9299-JZ	Date	Units
2			96413	Date	Units
3	0636	N400003232711ML10	J9228-JZ	Date	Units

SAMPLE

Enter the appropriate NDC 5010 format for OPDIVO® here:

- N400003377211ML4
- N400003377412ML10
- N400003375614ML12
- N400003373413ML24

Enter the appropriate NDC 5010 format for YERVOY® here:

- N400003232711ML10
- N400003232822ML40

Please contact the payer or BMS Access Support for additional information on coding and billing units. In addition to coding specifics, some payers may require additional information, such as a drug purchase invoice or documentation of medical necessity. 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.

REFERENCES

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

General Codes

The codes in this section may be appropriate when administering OPDIVO Qvantig™, OPDIVO®, and YERVOY®

References

References: 1. Centers for Medicare & Medicaid Services. Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy. Accessed December 16, 2024. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf **2.** Centers for Medicare & Medicaid Services. MLN Fact Sheet. November 2024. Accessed June 12, 2025. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf **3.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **4.** Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Determinations: First Quarter, 2025 HCPCS Coding Cycle. Accessed May 16, 2025. https://www.cms.gov/files/document/2025-hcpcs-application-summary-quarter-1-2025-drugs-and-biologicals.pdf **5.** National Uniform Billing Committee (NUBC). Official UB-04 Data Specifications Manual 2020. Chicago, IL: American Hospital Association; 2020. **6.** American Medical Association. CPT 2025 Professional Edition. American Medical Association; 2024. **7.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Revision 12671. June 6, 2024. Accessed December 16, 2024. http://www.cms.gov/ Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf **8.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25 – Completing and Processing the Form CMS-1450 Data Set. Revision 12423, December 20, 2023. Accessed December 16, 2024. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf **9.** OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **10.** American Medical Association. HCPCS Level II Expert 2025. American Medical Association; 2024. **11.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 17 – Drugs and Biologicals. Revision 12511. February 15, 2024. Accessed December 16, 2024. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf **12.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.

Melanoma: Adjuvant Therapy and Advanced Disease

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Adjuvant Treatment of Melanoma	**Adjuvant Treatment of Melanoma**
OPDIVO® OPDIVO® is indicated for the adjuvant treatment of adult and pediatric patients 12 years and older with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.	**OPDIVO Qvantig™** 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.
Unresectable or Metastatic Melanoma	**Unresectable or Metastatic Melanoma**
OPDIVO® OPDIVO®, as a single agent or in combination with YERVOY®, is indicated for the treatment of adult and pediatric patients 12 years of age and older with unresectable or metastatic melanoma.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy, or as monotherapy following treatment with OPDIVO® and YERVOY® (ipilimumab) combination therapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® for the treatment of unresectable or metastatic melanoma.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Melanoma: Adjuvant Therapy and Advanced Disease

Unresectable or Metastatic (Advanced) Melanoma[1,2]

OPDIVO® (nivolumab) injection, for intravenous use		OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use	
DOSING & SCHEDULE*† Dosing for adult and pediatric patients aged 12 years and older and weighing 40 kg or more‡		**DOSING & SCHEDULE**	
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W		**600 mg nivolumab and 10,000 units hyaluronidase§** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase§** Q4W	
DURATION		**DURATION**	
Adjuvant treatment of melanoma	until disease recurrence or unacceptable toxicity for up to 1 year	**Adjuvant treatment of melanoma**	until disease recurrence or unacceptable toxicity for up to 1 year
Advanced melanoma	until disease progression or unacceptable toxicity	**Advanced melanoma**	until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡For pediatric patients age 12 years and older and weighing less than 40 kg, OPDIVO® to be dosed 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks infused IV over 30 minutes.
§Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Melanoma: Adjuvant Therapy and Advanced Disease

Unresectable or Metastatic (Advanced) Melanoma[1,2,4]

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use following treatment with OPDIVO® and YERVOY® (ipilimumab)
DOSING & SCHEDULE[*†‡]	**DOSING & SCHEDULE**
Induction phase (weight-based)	
1 mg/kg of OPDIVO® IV infusion over 30 minutes Q3W **WITH** **3 mg/kg of YERVOY®** IV infusion over 30 minutes Q3W	**600 mg nivolumab and 10,000 units hyaluronidase[§]** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase[§]** Q4W
Maintenance phase	
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W	
DURATION	**DURATION**
Induction phase: In combination with YERVOY® for a maximum of 4 doses or until unacceptable toxicity, whichever occurs earlier	Following OPDIVO® and YERVOY® combination therapy, administer OPDIVO Qvantig™ as single agent until disease progression or unacceptable toxicity
Maintenance phase: After completing 4 doses of combination therapy, administer as single agent until disease progression or unacceptable toxicity	
Administer OPDIVO® first, followed by YERVOY® on the same day.	

[*]Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]

[†]Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]

[‡]For pediatric patients age 12 years and older and weighing less than 40 kg, OPDIVO® to be dosed with YERVOY® according to induction phase shown above, and OPDIVO® dosed for the maintenance phase 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks infused IV over 30 minutes until disease progression or unacceptable toxicity.

[§]Administer over 3-5 minutes.

IV=intravenous; Q2W=every two weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Melanoma: Adjuvant Therapy and Advanced Disease

ICD-10-CM CODES[5]

C43	**Malignant melanoma of skin**
C43.0	Malignant melanoma of lip
C43.1	Malignant melanoma of eyelid, including canthus*
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus*
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus*
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.2	Malignant melanoma of ear and external auricular canal*
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.3	Malignant melanoma of other and unspecified parts of face*
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.5	Malignant melanoma of trunk*
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk

*This is a category code and is invalid for stand-alone use.
Please select one of the expanded codes listed below.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Melanoma: Adjuvant Therapy and Advanced Disease

ICD-10-CM CODES[5] (continued)

C43.6	Malignant melanoma of upper limb, including shoulder*
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of other parts of face
C43.7	Malignant melanoma of lower limb, including hip*
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

The code C43 has an Excludes 2 note under it. Per ICD-10-CM official guidelines, an Excludes 2 note under a code represents “Not included here.” An Excludes 2 note indicates that the condition excluded is not part of the condition represented by the code, but a patient may have both conditions at the same time. When an Excludes 2 note appears under a code, it is acceptable to use both the code and the excluded code together, when appropriate.[5]

Under code C43, the Excludes 2 note lists the following[5]:

- Malignant melanoma of skin of genital organs (C51-C52, C60.-, C63.-)
- Merkel cell carcinoma (C4A.-)
- Sites other than skin – code to malignant neoplasm of the site

Melanoma: Adjuvant Therapy and Advanced Disease

ICD-10-CM CODES[5] (continued)

C21	Malignant neoplasm of anus and anal canal
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C51	Malignant neoplasm of vulva
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.9	Malignant neoplasm of vulva, unspecified
C52	Malignant neoplasm of vagina
C57	Malignant neoplasm of other and unspecified female genital organs
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C60	Malignant neoplasm of penis
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.8	Malignant neoplasm of overlapping sites of penis
C60.9	Malignant neoplasm of penis, unspecified
C63	Malignant neoplasm of other and unspecified male genital organs
C63.0	Malignant neoplasm of epididymis*
C63.00	Malignant neoplasm of unspecified epididymis
C63.01	Malignant neoplasm of right epididymis
C63.02	Malignant neoplasm of left epididymis

*This is a category code and is invalid for stand-alone use.
Please select one of the expanded codes listed below.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Melanoma: Adjuvant Therapy and Advanced Disease

ICD-10-CM CODES[5] (continued)

C63.1	Malignant neoplasm of spermatic cord*
C63.10	Malignant neoplasm of unspecified spermatic cord
C63.11	Malignant neoplasm of right spermatic cord
C63.12	Malignant neoplasm of left spermatic cord
C63.2	Malignant neoplasm of scrotum
C63.7	Malignant neoplasm of other specified male genital organs
C63.8	Malignant neoplasm of overlapping sites of male genital organs
C63.9	Malignant neoplasm of male genital organ, unspecified

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **4.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **5.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Neoadjuvant Treatment of Resectable NSCLC	**Neoadjuvant Treatment of Resectable NSCLC**
OPDIVO® + Chemotherapy OPDIVO®, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC.	**OPDIVO Qvantig™ + Chemotherapy** OPDIVO Qvantig™, in combination with platinum-doublet chemotherapy, is indicated as neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) NSCLC.
Neoadjuvant and Adjuvant Treatment of Resectable NSCLC	**Neoadjuvant and Adjuvant Treatment of Resectable NSCLC**
OPDIVO® + Chemotherapy OPDIVO®, 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 single-agent OPDIVO® as adjuvant treatment after surgery.	**OPDIVO Qvantig™ + Chemotherapy** 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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

INDICATIONS	RECOMMENDED DOSING	ICD-10-CM CODES	IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY®	IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use

1L mNSCLC (PD-L1 ≥1%)

OPDIVO® + YERVOY®

OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.

OPDIVO Qvantig™ is not indicated for this use.

1L Metastatic or Recurrent NSCLC

OPDIVO® + YERVOY® and 2 Cycles of Chemotherapy

OPDIVO®, in combination with YERVOY® and 2 cycles of platinum-doublet chemotherapy, is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC, with no EGFR or ALK genomic tumor aberrations.

OPDIVO Qvantig™ is not indicated for this use.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
2L mNSCLC	**2L mNSCLC**
OPDIVO® OPDIVO® 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®.	**OPDIVO Qvantig™** 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 YERVOY® for the treatment of metastatic NSCLC.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

Neoadjuvant Resectable NSCLC (tumors ≥4 cm or node positive)[1,2]

OPDIVO® (nivolumab) injection, for intravenous use + platinum-doublet chemotherapy	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use + platinum-doublet chemotherapy
DOSING & SCHEDULE*	**DOSING & SCHEDULE**
360 mg of OPDIVO® IV infusion over 30 minutes Q3W followed on the same day by platinum-doublet chemotherapy Q3W	**900 mg nivolumab and 15,000 units hyaluronidase†** **with platinum-doublet chemotherapy** on the same day Q3W
DURATION	**DURATION**
In combination with platinum-doublet chemotherapy for 3 cycles	In combination with platinum-doublet chemotherapy for 3 cycles
Administer OPDIVO® first, followed by platinum-doublet chemotherapy on the same day	

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

Neoadjuvant and Adjuvant Treatment of Resectable NSCLC[1,2]

OPDIVO® (nivolumab) injection, for intravenous use		OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use	
DOSING & SCHEDULE		**DOSING & SCHEDULE**	
Neoadjuvant	**360 mg of OPDIVO® IV infusion every 3 weeks* with platinum-doublet chemotherapy** on the same day Q3W	Neoadjuvant	**900 mg nivolumab and 15,000 units hyaluronidase† with platinum-doublet chemotherapy** on the same day Q3W
Adjuvant	**480 mg of OPDIVO® IV infusion** Q4W	Adjuvant	**1,200 mg nivolumab and 20,000 units hyaluronidase†** Q4W
DURATION		**DURATION**	
Neoadjuvant	In combination with chemotherapy for up to 4 cycles or until disease progression or unacceptable toxicity	Neoadjuvant	In combination with platinum-doublet chemotherapy until disease progression or unacceptable toxicity, for up to 4 cycles
Adjuvant	Following neoadjuvant therapy and surgery, administer OPDIVO® as a single agent for up to 13 cycles (approximately 1 year) or until disease recurrence or unacceptable toxicity	Adjuvant	Following neoadjuvant therapy and surgery, administer OPDIVO Qvantig™ as a single agent until disease progression, recurrence, or unacceptable toxicity, for up to 13 cycles (up to 1 year)

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

1L mNSCLC (PD-L1 ≥1%)[1,3]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use + YERVOY® (ipilimumab)

DOSING & SCHEDULE*

360 mg of OPDIVO®
IV infusion over
30 minutes Q3W

WITH

1 mg/kg of YERVOY®
IV infusion over
30 minutes Q6W

DURATION

In combination with YERVOY® until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression

Administer OPDIVO® first, followed by YERVOY® on the same day

OPDIVO Qvantig™ is not indicated for this use.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

1L Metastatic or Recurrent NSCLC[1,3]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) + YERVOY® (ipilimumab) with 2 cycles of histology-based platinum-doublet chemotherapy

DOSING & SCHEDULE*

OPDIVO® + YERVOY®

360 mg of OPDIVO® IV infusion over 30 minutes Q3W	WITH	1 mg/kg of YERVOY® IV infusion over 30 minutes Q6W

AND platinum-doublet chemotherapy

Histology-based platinum-doublet chemotherapy Q3W

DURATION

OPDIVO® + YERVOY®	Until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression
AND platinum-doublet chemotherapy	2 cycles of histology-based platinum-doublet chemotherapy

Administer OPDIVO® first, followed by YERVOY® on the same day.

Histology-based chemo; SQ patients: carboplatin AUC 6 + paclitaxel 200 mg/m^2 Q3W; NSQ patients: carboplatin AUC 5 or 6 or cisplatin 75 mg/m^2 + pemetrexed 500 mg/m^2 Q3W with optional pemetrexed maintenance therapy.[1]

For the r/m NSCLC dosing regimen in combination with chemo: on the first week, 4 agents will be administered (OPDIVO® 360 mg + YERVOY® 1 mg/kg + histology-based chemo) followed by 3 agents (OPDIVO® + histology-based chemo) on the third week, 2 agents (OPDIVO® + YERVOY®) on the sixth week, and OPDIVO® monotherapy on the ninth week, followed by maintenance therapy of OPDIVO® + YERVOY®.[1]

OPDIVO Qvantig™ is not indicated for this use.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

2L Metastatic Non-Small Cell Lung Cancer[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W	**600 mg nivolumab and 10,000 units hyaluronidase‡** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase‡** Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]
‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.
IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks; Q6W=every 6 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

ICD-10-CM CODES[5]

C33	**Malignant neoplasm of trachea**
C34	**Malignant neoplasm of bronchus and lung**
C34.0	Malignant neoplasm of main bronchus, carina, and hilus of lung*
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.1	Malignant neoplasm of upper lobe, bronchus or lung*
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.3	Malignant neoplasm of lower lobe, bronchus or lung*
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.8	Malignant neoplasm of overlapping sites of bronchus and lung*
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

(continued on next page)

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.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Non-Small Cell Lung Cancer (NSCLC): Metastatic/Recurrent or Early Stage

ICD-10-CM CODES[5] (continued)

C34.9	Malignant neoplasm of unspecified part of bronchus or lung*
C34.90	Malignant neoplasm of unspecified part of bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **4.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **5.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

1L Unresectable Malignant Pleural Mesothelioma (uMPM)

OPDIVO® (nivolumab) injection, for intravenous use

1L Unresectable Malignant Pleural Mesothelioma

OPDIVO® + YERVOY® (ipilimumab)

OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma (MPM).

OPDIVO Qvantig™ is not indicated for this use.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and YERVOY® are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1L Unresectable Malignant Pleural Mesothelioma (uMPM)

1L Unresectable Malignant Pleural Mesothelioma[1,2]

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE*

360 mg of OPDIVO® IV infusion over 30 minutes Q3W

WITH

1 mg/kg of YERVOY® IV infusion over 30 minutes Q6W

DURATION

In combination with YERVOY® until disease progression, unacceptable toxicity, or up to 2 years in patients without disease progression

Administer OPDIVO® first, followed by YERVOY® on the same day.

OPDIVO Qvantig™ is not indicated for this use.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q3W=every 3 weeks; Q6W=every 6 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

1L Unresectable Malignant Pleural Mesothelioma (uMPM)

ICD-10-CM CODES[3]

C45	Mesothelioma
C45.0	Malignant mesothelioma of pleura

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Advanced Renal Cell Carcinoma (RCC)

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
1L Intermediate or Poor Risk Advanced RCC	**1L Intermediate or Poor Risk Advanced RCC**
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC).	**OPDIVO Qvantig™** 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 OPDIVO® and YERVOY® combination therapy. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® for the treatment of renal cell carcinoma.
1L Advanced RCC	**1L Advanced RCC**
OPDIVO® + cabozantinib OPDIVO®, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).	**OPDIVO Qvantig™ + cabozantinib** OPDIVO Qvantig™, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Advanced Renal Cell Carcinoma (RCC)

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
2L Advanced RCC	**2L Advanced RCC**
OPDIVO® OPDIVO®, as a single agent, is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy, is indicated for the treatment of adult patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Advanced Renal Cell Carcinoma (RCC)

1L Intermediate or Poor Risk Advanced Renal Cell Carcinoma[1-3]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE*†

Induction Phase*† (weight-based)

3 mg/kg of OPDIVO® IV infusion over 30 minutes Q3W **WITH** **1 mg/kg of YERVOY®** IV infusion over 30 minutes Q3W

Maintenance Phase

240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W

DURATION

Induction Phase	In combination with YERVOY® for 4 doses
Maintenance Phase	After completing 4 doses of combination therapy with YERVOY®, administer as single agent until disease progression or unacceptable toxicity

Administer OPDIVO® first, followed by YERVOY® on the same day.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) use following treatment with OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE

Maintenance Phase

600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase‡** Q4W

DURATION

Following OPDIVO® + YERVOY® combination therapy, administer OPDIVO Qvantig™ as single agent until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]

‡Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Renal Cell Carcinoma (RCC)

1L Advanced Renal Cell Carcinoma[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) + cabozantinib	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use + cabozantinib
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
OPDIVO®	**OPDIVO Qvantig™**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** 480 mg of OPDIVO® IV infusion over 30 minutes Q4W	600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W **OR** 1,200 mg nivolumab and 20,000 units hyaluronidase‡ Q4W
Cabozantinib	**Cabozantinib**
Administer OPDIVO® in combination with **40 mg cabozantinib orally once daily without food**	Administer OPDIVO Qvantig™ in combination with **cabozantinib 40 mg orally once daily without food**
DURATION	**DURATION**
OPDIVO®: Until disease progression, unacceptable toxicity, or up to 2 years	**OPDIVO Qvantig™**: Until disease progression, unacceptable toxicity, or up to 2 years
Cabozantinib: Until disease progression or unacceptable toxicity	**Cabozantinib**: Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]

‡Administer over approximately 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Advanced Renal Cell Carcinoma (RCC)

2L Advanced Renal Cell Carcinoma[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** 480 mg of OPDIVO® IV infusion over 30 minutes Q4W	600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W **OR** 1,200 mg nivolumab and 20,000 units hyaluronidase‡ Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]

‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Renal Cell Carcinoma (RCC)

ICD-10-CM CODES[5]

C64	**Malignant neoplasm of kidney, except renal pelvis**
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65	**Malignant neoplasm of renal pelvis**
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **4.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **5.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

Classical Hodgkin Lymphoma (cHL)

OPDIVO® (nivolumab) injection, for intravenous use

2L Relapsed/Progressed Classical Hodgkin Lymphoma

OPDIVO®

OPDIVO® is indicated for the treatment of adult patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin or after 3 or more lines of systemic therapy that includes autologous HSCT.

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

OPDIVO Qvantig™ is not indicated for this use.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500178 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Classical Hodgkin Lymphoma (cHL)

Relapsed or Progressed Classical Hodgkin Lymphoma[1]

OPDIVO® (nivolumab) injection, for intravenous use

DOSING & SCHEDULE*†

240 mg of OPDIVO®
IV infusion over
30 minutes Q2W

OR

480 mg of OPDIVO®
IV infusion over
30 minutes Q4W

DURATION

Until disease progression or unacceptable toxicity

OPDIVO Qvantig™ is not indicated for this use.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[2]

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q2W=every 2 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500178 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Classical Hodgkin Lymphoma (cHL)

ICD-10-CM CODES[3]

C81	Hodgkin lymphoma
C81.1	Nodular sclerosis Hodgkin lymphoma*
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site
C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.2	Mixed cellularity Hodgkin lymphoma*
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

(continued on next page)

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.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500178 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Classical Hodgkin Lymphoma (cHL)

ICD-10-CM CODES[3] (continued)

C81.3	Lymphocyte depleted Hodgkin lymphoma*
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.4	Lymphocyte-rich Hodgkin lymphoma*
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

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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.

Classical Hodgkin Lymphoma (cHL)

ICD-10-CM CODES[3] (continued)

C81.7	Other Hodgkin lymphoma*
C81.70	Other Hodgkin lymphoma, unspecified site
C81.71	Other Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma, intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma, intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma, intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma, spleen
C81.78	Other Hodgkin lymphoma, lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma, extranodal and solid organ sites

*This is a category code and is invalid for stand-alone use. Please select one of the expanded codes listed below.

For patients who have had a stem cell transplant, add the following as a secondary code[3]:

Z94.84	Stem cells transplant status

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **3.** American Medical Association. 2024 ICD-10-CM: The Complete Official Codebook. Chicago, IL: American Medical Association; 2024.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
2L Squamous Cell Carcinoma of the Head and Neck	**2L Squamous Cell Carcinoma of the Head and Neck**
OPDIVO® (nivolumab) OPDIVO® 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.	**OPDIVO Qvantig™** 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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Recurrent or Metastatic SCCHN[1,2]

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W	**600 mg nivolumab and 10,000 units hyaluronidase‡** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase‡** Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]

‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q2W=every 2 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

ICD-10-CM CODES[4]

C00	**Malignant neoplasm of lip**
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip
C00.2	Malignant neoplasm of external lip, unspecified
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	**Malignant neoplasm of base of tongue**
C02	**Malignant neoplasm of other and unspecified parts of tongue**
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03	**Malignant neoplasm of gum**
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

ICD-10-CM CODES[4] (continued)

C04	**Malignant neoplasm of floor of mouth**
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05	**Malignant neoplasm of palate**
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06	**Malignant neoplasm of other and unspecified parts of mouth**
C06.0	Malignant neoplasm of cheek mucosa
C06.1	Malignant neoplasm of vestibule of mouth
C06.2	Malignant neoplasm of retromolar area
C06.8	Malignant neoplasm of overlapping sites of other and unspecified parts of the mouth*
C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09	**Malignant neoplasm of tonsil**
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified

*This is a category code and is invalid for stand-alone use.
Please select one of the expanded codes listed below.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

ICD-10-CM CODES[4] (continued)

C10	**Malignant neoplasm of oropharynx**
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C12	**Malignant neoplasm of pyriform sinus**
C13	**Malignant neoplasm of hypopharynx**
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14	**Malignant neoplasm of other and ill-defined sites in the lip, oral cavity and pharynx**
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

ICD-10-CM CODES[4] (continued)

C32	**Malignant neoplasm of larynx**
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C76	**Malignant neoplasm of other and ill-defined sites**
C76.0	Malignant neoplasm of head, face and neck

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **4.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

Urothelial Carcinoma (UC)

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Adjuvant Treatment of UC	**Adjuvant Treatment of UC**
OPDIVO® OPDIVO® 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™** 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.
1L Unresectable or Metastatic UC	**1L Unresectable or Metastatic UC**
OPDIVO® + Chemotherapy OPDIVO®, in combination with cisplatin and gemcitabine, is indicated as first-line treatment for adult patients with unresectable or metastatic urothelial carcinoma.	**OPDIVO Qvantig™ + Chemotherapy** OPDIVO Qvantig™, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Urothelial Carcinoma (UC)

OPDIVO® (nivolumab) injection, for intravenous use

2L Locally Advanced/Metastatic UC

OPDIVO®

OPDIVO® is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma 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.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use

2L Locally Advanced/Metastatic UC

OPDIVO Qvantig™

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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Urothelial Carcinoma (UC)

Locally Advanced or Metastatic and Adjuvant Therapy[1,2]

OPDIVO® (nivolumab) injection, for intravenous use			OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use		
DOSING & SCHEDULE*†			**DOSING & SCHEDULE**		
240 mg of OPDIVO® IV infusion over 30 minutes Q2W	OR	480 mg of OPDIVO® IV infusion over 30 minutes Q4W	600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W	OR	1,200 mg nivolumab and 20,000 units hyaluronidase‡ Q4W
DURATION			**DURATION**		
Locally advanced or metastatic	Until disease progression or unacceptable toxicity		**Locally advanced or metastatic**	Until disease progression or unacceptable toxicity	
Adjuvant	Until disease recurrence or unacceptable toxicity for up to 1 year		**Adjuvant**	Until disease recurrence or unacceptable toxicity for up to 1 year	

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Urothelial Carcinoma (UC)

1L Unresectable or Metastatic Urothelial Carcinoma[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use + Cisplatin and Gemcitabine	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use + Cisplatin and Gemcitabine
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
Combination Phase	**Combination Phase**
360 mg of OPDIVO® IV infusion over 30 minutes Q3W **WITH** Cisplatin and Gemcitabine on the same day Q3W	900 mg nivolumab and 15,000 units hyaluronidase‡ Q3W Administer OPDIVO Qvantig™ in combination with cisplatin and gemcitabine on the same day Q3W
Maintenance Phase	**Maintenance Phase**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** 480 mg of OPDIVO® IV infusion over 30 minutes Q4W	600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W **OR** 1,200 mg nivolumab and 20,000 units hyaluronidase‡ Q4W
DURATION	**DURATION**

Combination Phase	In combination with cisplatin and gemcitabine for up to 6 cycles	**Combination Phase**	In combination with cisplatin and gemcitabine for up to 6 cycles
Maintenance Phase	After completing up to 6 cycles of combination therapy, administer as single agent until disease progression, unacceptable toxicity, or up to 2 years from first dose	**Maintenance Phase**	After completing up to 6 cycles of combination therapy, administer as single agent until disease progression, unacceptable toxicity, or up to 2 years from first dose

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.
IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500053 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Urothelial Carcinoma (UC)

ICD-10-CM CODES[4]

C65	**Malignant neoplasm of renal pelvis**	**C68**	**Malignant neoplasm of other and unspecified urinary organ**
C65.1	Malignant neoplasm of the right renal pelvis	C68.0	Malignant neoplasm of urethra
C65.2	Malignant neoplasm of the left renal pelvis	C68.8	Malignant neoplasm of overlapping sites of urinary organs
C65.9	Malignant neoplasm of unspecified renal pelvis		
C66	**Malignant neoplasm of ureter**		
C66.1	Malignant neoplasm of the right ureter		
C66.2	Malignant neoplasm of the left ureter		
C66.9	Malignant neoplasm of unspecified ureter		
C67	**Malignant neoplasm of bladder**		
C67.0	Malignant neoplasm of trigone of bladder		
C67.1	Malignant neoplasm of dome of bladder		
C67.2	Malignant neoplasm of lateral wall of bladder		
C67.3	Malignant neoplasm of anterior wall of bladder		
C67.4	Malignant neoplasm of posterior wall of bladder		
C67.5	Malignant neoplasm of bladder neck		
C67.6	Malignant neoplasm of ureteric orifice		
C67.8	Malignant neoplasm of overlapping sites of bladder		
C67.9	Malignant neoplasm of bladder, unspecified		
C68.9	Malignant neoplasm of urinary organ, unspecified		

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **4.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

MSI-H/dMMR Metastatic Colorectal Cancer

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
MSI-H/dMMR Metastatic Colorectal Cancer	
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC). **OPDIVO®** OPDIVO®, as a single agent, is indicated for the treatment of adult and pediatric patients 12 years and older 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.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy or as monotherapy following treatment with intravenous OPDIVO® and YERVOY® combination therapy, is indicated for the treatment of adult patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® 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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

MSI-H/dMMR Metastatic Colorectal Cancer[1-3]

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE

Dosing for adult and pediatric patients aged 12 years and older and weighing 40 kg or more*

Induction phase

240 mg of OPDIVO® IV infusion over 30 minutes Q3W	WITH	**1 mg/kg of YERVOY®** IV infusion over 30 minutes Q3W

Maintenance Phase

240 mg of OPDIVO® IV infusion over 30 minutes Q2W	OR	**480 mg of OPDIVO®** IV infusion over 30 minutes Q4W

DURATION

Induction Phase	In combination with YERVOY® for a maximum of 4 doses
Maintenance Phase	After completing a maximum of 4 doses of combination therapy, administer as single agent until disease progression or unacceptable toxicity, or up to 2 years

Administer OPDIVO® first, followed by YERVOY® on the same day.

*For pediatric patients age 12 years and older and weighing less than 40 kg: OPDIVO® to be dosed 3 mg/kg every 3 weeks with YERVOY® 1 mg/kg infused IV over 30 minutes; after completing a maximum of 4 doses of combination therapy, administer OPDIVO® as a single agent dosed 3 mg/kg every 2 weeks or 6 mg/kg every 4 weeks, until disease progression or unacceptable toxicity, up to 2 years.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

MSI-H/dMMR Metastatic Colorectal Cancer[1-3]

OPDIVO® (nivolumab) injection, for intravenous use, monotherapy	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use, monotherapy
DOSING & SCHEDULE*†	**DOSING & SCHEDULE**
Dosing for adult and pediatric patients aged 12 years and older and weighing 40 kg or more‡	
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W	**600 mg nivolumab and 10,000 units hyaluronidase§** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase§** Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡For pediatric patients age 12 years and older and weighing less than 40 kg, OPDIVO® to be dosed 3 mg/kg every 2 weeks infused IV over 30 minutes until disease progression or unacceptable toxicity.
§Administer over approximately 3-5 minutes. These are dosing recommendations for both monotherapy or following intravenous nivolumab and ipilimumab combination therapy.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

1992-US-2500179 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

MSI-H/dMMR Metastatic Colorectal Cancer

ICD-10-CM CODES[4]

C18	**Malignant neoplasm of colon**
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	**Malignant neoplasm of rectosigmoid junction**
C20	**Malignant neoplasm of rectum**

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **4.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2024.

1992-US-2500179 04/25 OPDIVO Reimbursement & Coding Digital Reference Guide 2025

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Hepatocellular Carcinoma (HCC)

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
Unresectable or Metastatic Hepatocellular Carcinoma	
OPDIVO® + YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC). **OPDIVO® + YERVOY® (ipilimumab)** OPDIVO®, in combination with YERVOY®, is indicated for the treatment of adult patients with unresectable or metastatic HCC who have been previously treated with sorafenib.	**OPDIVO Qvantig™** OPDIVO Qvantig™, as monotherapy, is indicated for the treatment of adult patients with HCC who have been previously treated with sorafenib and following treatment with intravenous OPDIVO® and YERVOY®. Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® 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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and YERVOY® (ipilimumab) are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® is are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Hepatocellular Carcinoma (HCC)[1,2]

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE*†

Induction phase

1 mg/kg of OPDIVO® IV infusion over 30 minutes Q3W	WITH	**3 mg/kg of YERVOY®** IV infusion over 30 minutes Q3W

Maintenance Phase

240 mg of OPDIVO® IV infusion over 30 minutes Q2W	OR	**480 mg of OPDIVO®** IV infusion over 30 minutes Q4W

DURATION

Induction Phase	In combination with YERVOY® for a maximum of 4 doses
Maintenance Phase	Until disease progression, unacceptable toxicity, or up to 2 years

Administer OPDIVO® first, followed by YERVOY® on the same day.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]
‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.
IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Hepatocellular Carcinoma (HCC)[1-3]

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE*†

Induction phase

1 mg/kg of OPDIVO® IV infusion over 30 minutes Q3W	WITH	**3 mg/kg of YERVOY®** IV infusion over 30 minutes Q3W

Maintenance Phase

240 mg of OPDIVO® IV infusion over 30 minutes Q2W	OR	**480 mg of OPDIVO®** IV infusion over 30 minutes Q4W

DURATION

Induction Phase	In combination with YERVOY® for a maximum of 4 doses
Maintenance Phase	Until disease progression, unacceptable toxicity, or up to 2 years

Administer OPDIVO® first, followed by YERVOY® on the same day.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use following OPDIVO® + YERVOY® (ipilimumab) combination treatment

DOSING & SCHEDULE

600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W	OR	**1,200 mg nivolumab and 20,000 units hyaluronidase‡** Q4W

DURATION

Following OPDIVO® and YERVOY® combination therapy, administer OPDIVO Qvantig™ as single agent until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[4]
‡Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.
IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Advanced Hepatocellular Carcinoma (HCC)

ICD-10-CM CODES[5]

C22	**Malignant neoplasm of liver and intrahepatic bile ducts**
C22.0	Liver cell carcinoma (hepatocellular carcinoma, hepatoma)
C22.8	Malignant neoplasm of liver, primary, unspecified as to type

Z51.12	Encounter for antineoplastic immunotherapy

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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **4.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **5.** American Medical Association. 2024 ICD-10 CM: The Complete Official Codebook. Chicago, IL: American Medical Association; 2024.

Gastroesophageal Cancers: Metastatic and Adjuvant

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
1L Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma	**1L Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma**
OPDIVO® + Chemotherapy OPDIVO®, 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 whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™ + Chemotherapy** 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 whose tumors express PD-L1 (≥1).
Adjuvant Treatment of Completely Resected Esophageal Cancer or Gastroesophageal Junction Cancer	**Adjuvant Treatment of Completely Resected Esophageal Cancer or Gastroesophageal Junction Cancer**
OPDIVO® OPDIVO® 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™** 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).

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Gastroesophageal Cancers: Metastatic and Adjuvant

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma	**1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma**
OPDIVO®, in combination with fluoropyrimidine- and platinum-containing chemotherapy OPDIVO®, 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) whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™, in combination with fluoropyrimidine- and platinum-containing chemotherapy** 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) whose tumors express PD-L1 (≥1). Limitations of Use: OPDIVO Qvantig™ is not indicated in combination with YERVOY® for the treatment of patients with unresectable advanced or metastatic ESCC.
1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma	
OPDIVO®, in combination with YERVOY® (ipilimumab) OPDIVO®, in combination with YERVOY® (ipilimumab), is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).	**OPDIVO Qvantig™ not indicated for combination use with YERVOY®.**

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO®, YERVOY®, and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
2L Unresectable Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma	**2L Unresectable Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma**
OPDIVO® OPDIVO® is indicated for the treatment of adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.	**OPDIVO Qvantig™** 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.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO® and OPDIVO Qvantig™ are 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; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO® and OPDIVO Qvantig™ are added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Gastroesophageal Cancers: Metastatic and Adjuvant

Advanced or Metastatic Gastric Cancer, Gastroesophageal Junction Cancer, or Esophageal Adenocarcinoma[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) with fluoropyrimidine- and platinum-containing chemotherapy	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) with fluoropyrimidine- and platinum-containing chemotherapy
DOSING & SCHEDULE*	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes with fluoropyrimidine- and platinum-containing chemotherapy Q2W **OR** **360 mg of OPDIVO®** IV infusion over 30 minutes with fluoropyrimidine- and platinum-containing chemotherapy Q3W	**600 mg nivolumab and 10,000 units hyaluronidase† with fluoropyrimidine- and platinum-containing chemotherapy** Q2W **OR** **900 mg nivolumab and 15,000 units hyaluronidase† with fluoropyrimidine- and platinum-containing chemotherapy** Q3W
DURATION	**DURATION**
Until disease progression, unacceptable toxicity, or up to 2 years	**OPDIVO Qvantig™**: Until disease progression, unacceptable toxicity, or up to 2 years
Administer OPDIVO® first, followed by fluoropyrimidine- and platinum-containing chemotherapy on the same day.	**Chemotherapy**: Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]

†Administer over 3-5 minutes.

Please see the US Full Prescribing Information, Section 2, Dosing & Administration, for information on Dose Modifications, including interruption and discontinuation.

IV=intravenous; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks; Q6W=every 6 weeks.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

Adjuvant Treatment of Completely Resected Esophageal Cancer or Gastroesophageal Junction Cancer[1,2]

OPDIVO® (nivolumab) injection, for intravenous use	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use
DOSING & SCHEDULE *†	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** **480 mg of OPDIVO®** IV infusion over 30 minutes Q4W	**600 mg nivolumab and 10,000 units hyaluronidase‡** Q2W **OR** **1,200 mg nivolumab and 20,000 units hyaluronidase‡** Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity for a total treatment duration of 1 year	Until disease recurrence or unacceptable toxicity for up to 1 year

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma[1,2]

OPDIVO® (nivolumab) with fluoropyrimidine- and platinum-containing chemotherapy

DOSING & SCHEDULE*†

OPDIVO®

240 mg of OPDIVO® IV infusion over 30 minutes Q2W

OR

480 mg of OPDIVO® IV infusion over 30 minutes Q4W

Chemotherapy

Administer OPDIVO® in combination with fluoropyrimidine- and platinum-containing chemotherapy

DURATION

OPDIVO®	Until disease progression, unacceptable toxicity, or up to 2 years
Chemotherapy	Until disease progression or unacceptable toxicity

Administer OPDIVO® first, followed by fluoropyrimidine- and platinum-containing chemotherapy on the same day.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use with fluoropyrimidine- and platinum-containing chemotherapy

DOSING & SCHEDULE

600 mg nivolumab and 10,000 units hyaluronidase‡ with fluoropyrimidine- and platinum-containing chemotherapy Q2W

OR

1,200 mg nivolumab and 20,000 units hyaluronidase‡ with fluoropyrimidine- and platinum-containing chemotherapy Q4W

DURATION

OPDIVO Qvantig™	Until disease progression, unacceptable toxicity, or up to 2 years
Chemotherapy	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure–response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡30-minute intravenous infusion on the same day.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

1L Unresectable Advanced or Metastatic Esophageal Squamous Cell Carcinoma[1,4]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) + YERVOY® (ipilimumab)

DOSING & SCHEDULE*†

3 mg/kg of OPDIVO®
IV infusion over
30 minutes Q2W

OR

360 mg of OPDIVO®
IV infusion over
30 minutes Q3W

WITH

1 mg/kg of YERVOY®
IV infusion over
30 minutes Q6W

DURATION

In combination with YERVOY® (ipilimumab) until disease progression, unacceptable toxicity, or up to 2 years

Administer OPDIVO® first, followed by YERVOY® on the same day.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is not indicated for combination use with YERVOY®.

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® or OPDIVO® + YERVOY® in patients with severe or life-threatening infusion-related reactions.[1]

†30-minute intravenous infusion on the same day.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

2L Unresectable Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma[1,2]

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

OPDIVO® (nivolumab) injection, for intravenous use, monotherapy	OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) injection, for subcutaneous use, monotherapy
DOSING & SCHEDULE *†	**DOSING & SCHEDULE**
240 mg of OPDIVO® IV infusion over 30 minutes Q2W **OR** 480 mg of OPDIVO® IV infusion over 30 minutes Q4W	600 mg nivolumab and 10,000 units hyaluronidase‡ Q2W **OR** 1,200 mg nivolumab and 20,000 units hyaluronidase‡ Q4W
DURATION	**DURATION**
Until disease progression or unacceptable toxicity	Until disease progression or unacceptable toxicity

*Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Discontinue OPDIVO® in patients with severe or life-threatening infusion-related reactions.[1]
†Based on exploratory dose-exposure-response relationships for efficacy and safety, OPDIVO® 240 mg Q2W and 480 mg Q4W are predicted to be similar.[3]
‡Administer over 3-5 minutes.

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Gastroesophageal Cancers: Metastatic and Adjuvant

INDICATIONS | RECOMMENDED DOSING | ICD-10-CM CODES | IMPORTANT SAFETY INFORMATION OPDIVO® + YERVOY® | IMPORTANT SAFETY INFORMATION OPDIVO Qvantig™

ICD-10-CM CODES[5]

Code	Diagnosis	Advanced ESCC	Adjuvant Treatment of EC or GEJC	1L Metastatic ESCC	Advanced or Metastatic Gastric, GEJ, and Esophageal Adenocarcinoma
C15	Malignant neoplasm of esophagus	✓	✓	✓	✓
C15.3	Malignant neoplasm of upper third of esophagus	✓	✓	✓	✓
C15.4	Malignant neoplasm of middle third of esophagus	✓	✓	✓	✓
C15.5	Malignant neoplasm of lower third of esophagus	✓	✓	✓	✓
C15.8	Malignant neoplasm of overlapping sites of esophagus	✓	✓	✓	✓
C15.9	Malignant neoplasm of esophagus, unspecified	✓	✓	✓	✓
C16	Malignant neoplasm of stomach (gastroesophageal junction)		✓		✓
C16.0	Malignant neoplasm of cardia*		✓		✓
C16.1	Malignant neoplasm of fundus of stomach				✓
C16.2	Malignant neoplasm of body of stomach				✓
C16.3	Malignant neoplasm of pyloric antrum				✓
C16.4	Malignant neoplasm of pylorus				✓
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified				✓
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified				✓
C16.8	Malignant neoplasm of overlapping sites of stomach				✓
C16.9	Malignant neoplasm of stomach, unspecified				✓

Z51.12	Encounter for antineoplastic immunotherapy

*Applicable to malignant neoplasm of: cardiac orifice, cardio-esophageal junction, esophagus and stomach, gastro-esophageal junction. 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.

References: 1. OPDIVO® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** OPDIVO Qvantig™ [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **3.** Long GV, Tykodi SS, Schneider JG, et al. Assessment of nivolumab exposure and clinical safety of 480 mg every 4 weeks flat-dosing schedule in patients with cancer. *Ann Oncol*. 2018;29(11):2208-2213. **4.** YERVOY® [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **5.** American Medical Association. ICD-10-CM Expert 2025. American Medical Association; 2020.

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab)

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions listed herein may not include all possible 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®. Early identification and management are essential to ensure safe use of OPDIVO®. 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 with OPDIVO®. 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® depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO® 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 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® can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients receiving OPDIVO® monotherapy, immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.9%), and Grade 2 (2.1%).

In Checkmate 205 and 039, pneumonitis, including interstitial lung disease, occurred in 6.0% (16/266) of patients receiving OPDIVO®. Immune-mediated pneumonitis occurred in 4.9% (13/266) of patients receiving OPDIVO®, including Grade 3 (n=1) and Grade 2 (n=12).

Immune-Mediated Colitis
OPDIVO® 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. In patients receiving OPDIVO® monotherapy, immune-mediated colitis occurred in 2.9% (58/1994) of patients, including Grade 3 (1.7%) and Grade 2 (1%).

Immune-Mediated Hepatitis and Hepatotoxicity
OPDIVO® can cause immune-mediated hepatitis. In patients receiving OPDIVO® monotherapy, immune-mediated hepatitis occurred in 1.8% (35/1994) of patients, including Grade 4 (0.2%), Grade 3 (1.3%), and Grade 2 (0.4%).

OPDIVO® in combination with cabozantinib can cause hepatic toxicity with higher frequencies of Grade 3 and 4 ALT and AST elevations compared to OPDIVO® alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are administered as single agents. In patients receiving OPDIVO® and cabozantinib, Grades 3 and 4 increased ALT or AST were seen in 11% of patients.

Immune-Mediated Endocrinopathies
OPDIVO® can cause primary or secondary adrenal insufficiency, immune-mediated hypophysitis, immune-mediated thyroid disorders, and Type 1 diabetes mellitus,

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which can present with diabetic ketoacidosis. Withhold OPDIVO® 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.

In patients receiving OPDIVO® monotherapy, adrenal insufficiency occurred in 1% (20/1994), including Grade 3 (0.4%) and Grade 2 (0.6%). In patients receiving OPDIVO® and cabozantinib, adrenal insufficiency occurred in 4.7% (15/320) of patients, including Grade 3 (2.2%) and Grade 2 (1.9%).

In patients receiving OPDIVO® monotherapy, hypophysitis occurred in 0.6% (12/1994) of patients, including Grade 3 (0.2%) and Grade 2 (0.3%).

In patients receiving OPDIVO® monotherapy, thyroiditis occurred in 0.6% (12/1994) of patients, including Grade 2 (0.2%).

In patients receiving OPDIVO® monotherapy, hyperthyroidism occurred in 2.7% (54/1994) of patients, including Grade 3 (<0.1%) and Grade 2 (1.2%).

In patients receiving OPDIVO® monotherapy, hypothyroidism occurred in 8% (163/1994) of patients, including Grade 3 (0.2%) and Grade 2 (4.8%).

In patients receiving OPDIVO® monotherapy, diabetes occurred in 0.9% (17/1994) of patients, including Grade 3 (0.4%) and Grade 2 (0.3%), and 2 cases of diabetic ketoacidosis.

Immune-Mediated Nephritis with Renal Dysfunction

OPDIVO® can cause immune-mediated nephritis. In patients receiving OPDIVO® monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.5%), and Grade 2 (0.6%).

Immune-Mediated Dermatologic Adverse Reactions

OPDIVO® can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) 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® depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

In patients receiving OPDIVO® monotherapy, immune-mediated rash occurred in 9% (171/1994) of patients, including Grade 3 (1.1%) and Grade 2 (2.2%).

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® monotherapy 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

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

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IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) (cont'd)

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, which has been observed in patients receiving OPDIVO®, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Infusion-Related Reactions
OPDIVO® can cause severe infusion-related reactions. Discontinue OPDIVO® in patients with severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild (Grade 1) or moderate (Grade 2) infusion-related reactions. In patients receiving OPDIVO® monotherapy as a 60-minute infusion, infusion-related reactions occurred in 6.4% (127/1994) of patients. In a separate trial in which patients received OPDIVO® monotherapy as a 60-minute infusion or a 30-minute infusion, infusion-related reactions occurred in 2.2% (8/368) and 2.7% (10/369) of patients, respectively. Additionally, 0.5% (2/368) and 1.4% (5/369) of patients, respectively, experienced adverse reactions within 48 hours of infusion that led to dose delay, permanent discontinuation or withholding of OPDIVO®.

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®. 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® and allogeneic HSCT.

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

Embryo-Fetal Toxicity
Based on its mechanism of action and findings from animal studies, OPDIVO® can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO® and for at least 5 months after the last dose.

Increased Mortality in Patients with Multiple Myeloma when OPDIVO® is Added to a Thalidomide Analogue and Dexamethasone
In randomized clinical trials in patients with multiple myeloma, the addition of OPDIVO® to a thalidomide analogue plus dexamethasone 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 OPDIVO® in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 5 months after the last dose.

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Serious Adverse Reactions

In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO® (n=268). Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO®. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO® were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO® (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO®. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO® were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). In Checkmate 067, the most frequent (≥10%) serious adverse reactions in the OPDIVO® arm (n=313) were diarrhea (2.2%), colitis (1.9%), and pyrexia (1.0%). In Checkmate 238, serious adverse reactions occurred in 18% of patients receiving OPDIVO® (n=452). Grade 3 or 4 adverse reactions occurred in 25% of OPDIVO®-treated patients (n=452). The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of OPDIVO®-treated patients were diarrhea and increased lipase and amylase. In Checkmate 816, serious adverse reactions occurred in 30% of patients (n=176) who were treated with OPDIVO® in combination with platinum-doublet chemotherapy. Serious adverse reactions in >2% included pneumonia and vomiting. No fatal adverse reactions occurred in patients who received OPDIVO® in combination with platinum-doublet chemotherapy. In Checkmate 77T, serious adverse reactions occurred in 21% of patients who received OPDIVO® 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 OPDIVO® (n=418). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO® 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 9ER, serious adverse reactions occurred in 48% of patients receiving OPDIVO® 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 OPDIVO® (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 205 and 039, adverse reactions leading to discontinuation occurred in 7% and dose delays due to adverse reactions occurred in 34% of patients (n=266). Serious adverse reactions occurred in 26% of patients. The most frequent serious adverse reactions reported in ≥1% of patients were pneumonia, infusion-related reaction, pyrexia, colitis or diarrhea, pleural effusion, pneumonitis, and rash. Eleven patients died from causes other than disease progression: 3 from adverse reactions within 30 days of the last OPDIVO® dose, 2 from infection 8 to 9 months after completing OPDIVO®, and 6 from complications of allogeneic HSCT. In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving OPDIVO® (n=236). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO® were pneumonia, dyspnea, respiratory failure, respiratory tract infection, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving OPDIVO® (n=270). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO® 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 OPDIVO® (n=351). The most frequent serious adverse reaction reported in ≥2% of patients receiving OPDIVO® was urinary tract infection. Fatal

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

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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 OPDIVO® in combination with chemotherapy. The most frequent serious adverse reactions reporting in ≥2% of patients who received OPDIVO® 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 OPDIVO® in combination with chemotherapy; these included sepsis (1%). OPDIVO® and/or chemotherapy were discontinued in 30% of patients and were delayed in 67% of patients for an adverse reaction. In Checkmate 8HW, serious adverse reactions occurred in 39% of patients receiving OPDIVO® alone. The most frequent serious adverse reactions reported in >1% of patients who received OPDIVO® as a single agent were intestinal obstruction (2.3%), acute kidney injury (1.7%), COVID-19 (1.7%), abdominal pain (1.4%), diarrhea (1.4%), ileus (1.4%), subileus (1.4%), pulmonary embolism (1.4%), adrenal insufficiency (1.1%) and pneumonia (1.1%). Fatal adverse reactions occurring in 3 (0.9%) patients who received OPDIVO® as a single agent; these included pneumonitis (n=2) and myasthenia gravis. In Attraction-3, serious adverse reactions occurred in 38% of patients receiving OPDIVO® (n=209). Serious adverse reactions reported in ≥2% of patients who received OPDIVO® were pneumonia, esophageal fistula, interstitial lung disease, and pyrexia. The following fatal adverse reactions occurred in patients who received OPDIVO®: 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 OPDIVO® (n=532). A serious adverse reaction reported in ≥2% of patients who received OPDIVO® was pneumonitis. A fatal reaction of myocardial infarction occurred in one patient who received OPDIVO®. In Checkmate 648, serious adverse reactions occurred in 62% of patients receiving OPDIVO® in combination with chemotherapy (n=310). The most frequent serious adverse reactions reported in ≥2% of patients who received OPDIVO® 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, and acute kidney injury. In Checkmate 649, serious adverse reactions occurred in 52% of patients treated with OPDIVO® in combination with chemotherapy (n=782). The most frequent serious adverse reactions reported in ≥2% of patients treated with OPDIVO® 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 OPDIVO® 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 OPDIVO® (n=524). Adverse reactions which resulted in permanent discontinuation of OPDIVO® 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 ≥1% of OPDIVO®- 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 037, the most common adverse reaction (≥20%) reported with OPDIVO® (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO® (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 (≥20%) adverse reactions in the OPDIVO® 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

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OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

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(22%), constipation (21%), arthralgia (21%), and vomiting (20%). In Checkmate 238, the most common adverse reactions (≥20%) reported in OPDIVO®-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 Checkmate 816, the most common (>20%) adverse reactions in the OPDIVO® 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 ≥20%) in patients receiving OPDIVO® 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 (≥20%) in patients receiving OPDIVO® (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 9ER, the most common adverse reactions (≥20%) in patients receiving OPDIVO® and cabozantinib (n=320) were diarrhea (64%), fatigue (51%), hepatotoxicity (44%), palmar-plantar erythrodysaesthesia 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 (≥20%) reported in patients receiving OPDIVO® (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 205 and 039, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO® (n=266) were upper respiratory tract infection (44%), fatigue (39%), cough (36%), diarrhea (33%), pyrexia (29%), musculoskeletal pain (26%), rash (24%), nausea (20%) and pruritus (20%). In Checkmate 141, the most common adverse reactions (≥10%) in patients receiving OPDIVO® (n=236) were cough (14%) and dyspnea (14%) at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO® (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 OPDIVO® (n=351) were rash (36%), fatigue (36%), diarrhea (30%), pruritus (30%), musculoskeletal pain (28%), and urinary tract infection (22%). In Checkmate 901, the most common adverse reactions (≥20%) were nausea, fatigue, musculoskeletal pain, constipation, decreased appetite, rash, vomiting, and peripheral neuropathy. In Checkmate 8HW the most common adverse reaction reported in ≥20% of patients treated with OPDIVO® as a single agent, were fatigue, diarrhea, abdominal pain, pruritus, and musculoskeletal pain. In Attraction-3, the most common adverse reactions (≥20%) in OPDIVO®-treated patients (n=209) were rash (22%) and decreased appetite (21%). In Checkmate 577, the most common adverse reactions (≥20%) in patients receiving OPDIVO® (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 (≥20%) in patients treated with OPDIVO® in combination with chemotherapy (n=310) were nausea, decreased appetite, fatigue, constipation, stomatitis, diarrhea, and vomiting. In Checkmate 649, the most common adverse reactions (≥20%) in patients treated with OPDIVO® in combination with chemotherapy (n=782) were peripheral neuropathy, nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation, and musculoskeletal pain. In Checkmate 76K, the most common adverse reactions (≥20%) reported with OPDIVO® (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 OPDIVO®-treated patients who received neoadjuvant treatment, did not receive surgery due to adverse reactions. The adverse reactions that led to cancellation of surgery in OPDIVO®-treated patients

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were cerebrovascular accident, pneumonia, and colitis/diarrhea (2 patients each) and acute coronary syndrome, myocarditis, hemoptysis, pneumonitis, COVID-19, and myositis (1 patient each).

Clinical Trials and Patient Populations
Checkmate 649–previously untreated advanced or metastatic gastric cancer, gastroesophageal junction and esophageal adenocarcinoma; Checkmate 577–adjuvant treatment of esophageal or gastroesophageal junction cancer; Checkmate 238–adjuvant treatment of patients with completely resected Stage III or Stage IV melanoma; Checkmate 76K–adjuvant treatment of patients 12 years of age and older with completely resected Stage IIB or Stage IIC melanoma; Checkmate 274–adjuvant treatment of urothelial carcinoma; Checkmate 275 previously treated advanced or metastatic urothelial carcinoma; 8HW: Previously Checkmate 142–MSI-H or dMMR metastatic colorectal cancer, as a single agent; Attraction-3–esophageal squamous cell carcinoma; Checkmate 648—previously untreated, unresectable advanced recurrent or metastatic esophageal squamous cell carcinoma in combination with chemotherapy; Checkmate 037–previously treated metastatic melanoma; Checkmate 066—previously untreated metastatic melanoma; Checkmate 017–second-line treatment of metastatic squamous non-small cell lung cancer; Checkmate 057–second-line treatment of metastatic non-squamous non-small cell lung cancer; Checkmate 816–neoadjuvant non-small cell lung cancer, in combination with platinum-doublet chemotherapy; Checkmate 77T–Neoadjuvant treatment with platinum-doublet chemotherapy for non-small cell lung cancer followed by single-agent OPDIVO® as adjuvant treatment after surgery; Checkmate 901–Adult patients with unresectable or metastatic urothelial carcinoma; Checkmate 141–recurrent or metastatic squamous cell carcinoma of the head and neck; Checkmate 025–previously treated renal cell carcinoma; Checkmate 9ER–previously untreated renal cell carcinoma, in combination with cabozantinib; Checkmate 205/039–classical Hodgkin lymphoma.

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Important Safety Information

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Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions listed herein may not include all possible 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 or YERVOY. Early identification and management are essential to ensure safe use of OPDIVO and YERVOY. Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, adrenocorticotropic hormone (ACTH) level, and thyroid function at baseline and periodically during treatment with OPDIVO and before each dose of YERVOY. 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 and YERVOY depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO or YERVOY 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 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 and YERVOY can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

In patients receiving OPDIVO monotherapy, immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.9%), and Grade 2 (2.1%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, immune-mediated pneumonitis occurred in 7% (31/456) of patients, including Grade 4 (0.2%), Grade 3 (2.0%), and Grade 2 (4.4%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated pneumonitis occurred in 3.9% (26/666) of patients, including Grade 3 (1.4%) and Grade 2 (2.6%). In NSCLC patients receiving OPDIVO 3 mg/kg every 2 weeks with YERVOY 1 mg/kg every 6 weeks, immune-mediated pneumonitis occurred in 9% (50/576) of patients, including Grade 4 (0.5%), Grade 3 (3.5%), and Grade 2 (4.0%). Four patients (0.7%) died due to pneumonitis.

In Checkmate 205 and 039, pneumonitis, including interstitial lung disease, occurred in 6.0% (16/266) of patients receiving OPDIVO. Immune-mediated pneumonitis occurred in 4.9% (13/266) of patients receiving OPDIVO, including Grade 3 (n=1) and Grade 2 (n=12).

Immune-Mediated Colitis

OPDIVO and YERVOY can cause immune-mediated colitis, which may be fatal. 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. In patients receiving OPDIVO monotherapy, immune-mediated colitis occurred in 2.9% (58/1994) of patients, including Grade 3 (1.7%) and Grade 2 (1%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, immune-mediated colitis occurred in 25% (115/456) of patients, including Grade 4 (0.4%), Grade 3 (14%) and Grade 2 (8%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated colitis occurred in 9% (60/666) of patients, including Grade 3 (4.4%) and Grade 2 (3.7%).

Please see Important Safety Information for OPDIVO®, OPDIVO® and YERVOY® (ipilimumab), and OPDIVO Qvantig™, and US Full Prescribing Information for OPDIVO®, OPDIVO Qvantig™, and YERVOY®. For reimbursement assistance, call BMS Access Support® at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday, or visit www.BMSAccessSupport.com.

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

Immune-Mediated Hepatitis and Hepatotoxicity

OPDIVO and YERVOY can cause immune-mediated hepatitis. In patients receiving OPDIVO monotherapy, immune-mediated hepatitis occurred in 1.8% (35/1994) of patients, including Grade 4 (0.2%), Grade 3 (1.3%), and Grade 2 (0.4%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, immune-mediated hepatitis occurred in 15% (70/456) of patients, including Grade 4 (2.4%), Grade 3 (11%), and Grade 2 (1.8%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated hepatitis occurred in 7% (48/666) of patients, including Grade 4 (1.2%), Grade 3 (4.9%), and Grade 2 (0.4%).

OPDIVO in combination with cabozantinib can cause hepatic toxicity with higher frequencies of Grade 3 and 4 ALT and AST elevations compared to OPDIVO alone. Consider more frequent monitoring of liver enzymes as compared to when the drugs are administered as single agents. In patients receiving OPDIVO and cabozantinib, Grades 3 and 4 increased ALT or AST were seen in 11% of patients.

Immune-Mediated Endocrinopathies

OPDIVO and YERVOY 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 and YERVOY 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.

In patients receiving OPDIVO monotherapy, adrenal insufficiency occurred in 1% (20/1994), including Grade 3 (0.4%) and Grade 2 (0.6%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, adrenal insufficiency occurred in 8% (35/456) of patients, including Grade 4 (0.2%), Grade 3 (2.4%), and Grade 2 (4.2%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, adrenal insufficiency occurred in 7% (48/666) of patients, including Grade 4 (0.3%), Grade 3 (2.5%), and Grade 2 (4.1%). In patients receiving OPDIVO and cabozantinib, adrenal insufficiency occurred in 4.7% (15/320) of patients, including Grade 3 (2.2%) and Grade 2 (1.9%).

In patients receiving OPDIVO monotherapy, hypophysitis occurred in 0.6% (12/1994) of patients, including Grade 3 (0.2%) and Grade 2 (0.3%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, hypophysitis occurred in 9% (42/456) of patients, including Grade 3 (2.4%) and Grade 2 (6%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hypophysitis occurred in 4.4% (29/666) of patients, including Grade 4 (0.3%), Grade 3 (2.4%), and Grade 2 (0.9%).

In patients receiving OPDIVO monotherapy, thyroiditis occurred in 0.6% (12/1994) of patients, including Grade 2 (0.2%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, thyroiditis occurred in 2.7% (22/666) of patients, including Grade 3 (4.5%) and Grade 2 (2.2%).

In patients receiving OPDIVO monotherapy, hyperthyroidism occurred in 2.7% (54/1994) of patients, including Grade 3 (<0.1%) and Grade 2 (1.2%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, hyperthyroidism occurred in 9% (42/456) of patients, including Grade 3 (0.9%) and Grade 2 (4.2%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hyperthyroidism occurred in 12% (80/666) of patients, including Grade 3 (0.6%) and Grade 2 (4.5%).

In patients receiving OPDIVO monotherapy, hypothyroidism occurred in 8% (163/1994) of patients, including Grade 3 (0.2%) and Grade 2 (4.8%). In patients

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Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, hypothyroidism occurred in 20% (91/456) of patients, including Grade 3 (0.4%) and Grade 2 (11%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hypothyroidism occurred in 18% (122/666) of patients, including Grade 3 (0.6%) and Grade 2 (11%).

In patients receiving OPDIVO monotherapy, diabetes occurred in 0.9% (17/1994) of patients, including Grade 3 (0.4%) and Grade 2 (0.3%), and 2 cases of diabetic ketoacidosis. In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, diabetes occurred in 2.7% (15/666) of patients, including Grade 4 (0.6%), Grade 3 (0.3%), and Grade 2 (0.9%).

Immune-Mediated Nephritis with Renal Dysfunction

OPDIVO and YERVOY can cause immune-mediated nephritis. In patients receiving OPDIVO monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.5%), and Grade 2 (0.6%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated nephritis with renal dysfunction occurred in 4.1% (27/666) of patients, including Grade 4 (0.6%), Grade 3 (1.1%), and Grade 2 (2.2%).

Immune-Mediated Dermatologic Adverse Reactions

OPDIVO can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) 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.

YERVOY can cause immune-mediated rash or dermatitis, including bullous and exfoliative dermatitis, SJS, TEN, and DRESS. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/ exfoliative rashes.

Withhold or permanently discontinue OPDIVO and YERVOY depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).

In patients receiving OPDIVO monotherapy, immune-mediated rash occurred in 9% (171/1994) of patients, including Grade 3 (1.1%) and Grade 2 (2.2%). In patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, immune-mediated rash occurred in 28% (127/456) of patients, including Grade 3 (4.8%) and Grade 2 (10%). In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated rash occurred in 16% (108/666) of patients, including Grade 3 (3.5%) and Grade 2 (4.2%).

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 monotherapy or OPDIVO in combination with YERVOY 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.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

In addition to the immune-mediated adverse reactions listed above, across clinical trials of YERVOY monotherapy or in combination with OPDIVO, the following clinically significant immune-mediated adverse reactions, some with fatal outcome, occurred in <1% of patients unless otherwise specified: *nervous system*: autoimmune neuropathy (2%), myasthenic syndrome/myasthenia gravis, motor dysfunction; *cardiovascular*: angiopathy, temporal arteritis; *ocular*: blepharitis, episcleritis, orbital myositis, scleritis; *gastrointestinal*: pancreatitis (1.3%); *other (hematologic/immune)*: conjunctivitis, cytopenias (2.5%), eosinophilia (2.1%), erythema multiforme, hypersensitivity vasculitis, neurosensory hypoacusis, psoriasis.

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, which has been observed in patients receiving OPDIVO and YERVOY, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Infusion-Related Reactions

OPDIVO and YERVOY can cause severe infusion-related reactions. Discontinue OPDIVO and YERVOY in patients with severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild (Grade 1) or moderate (Grade 2) infusion-related reactions. In patients receiving OPDIVO monotherapy as a 60-minute infusion, infusion-related reactions occurred in 6.4% (127/1994) of patients. In a separate trial in which patients received OPDIVO monotherapy as a 60-minute infusion or a 30-minute infusion, infusion-related reactions occurred in 2.2% (8/368) and 2.7% (10/369) of patients, respectively. Additionally, 0.5% (2/368) and 1.4% (5/369) of patients, respectively, experienced adverse reactions within 48 hours of infusion that led to dose delay, permanent discontinuation or withholding of OPDIVO. In melanoma patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, infusion-related reactions occurred in 2.5% (10/407) of patients. In HCC patients receiving OPDIVO 1 mg/kg with YERVOY 3 mg/kg every 3 weeks, infusion-related reactions occurred in 8% (4/49) of patients. In RCC patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, infusion-related reactions occurred in 5.1% (28/547) of patients. In MSI- H/dMMR mCRC patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, infusion-related reactions occurred in 4.2% (5/119) of patients. In MPM patients receiving OPDIVO 3 mg/kg every 2 weeks with YERVOY 1 mg/kg every 6 weeks, infusion-related reactions occurred in 12% (37/300) of patients.

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 or YERVOY. 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 or YERVOY and allogeneic HSCT.

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

Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal studies, OPDIVO and YERVOY can cause fetal harm when administered to a pregnant woman. The effects of YERVOY are likely to be greater during the second and third trimesters of pregnancy. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO and YERVOY and for at least 5 months after the last dose.

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Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

Increased Mortality in Patients with Multiple Myeloma when OPDIVO is Added to a Thalidomide Analogue and Dexamethasone

In randomized clinical trials in patients with multiple myeloma, the addition of OPDIVO to a thalidomide analogue plus dexamethasone 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 OPDIVO or YERVOY in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 5 months after the last dose.

Serious Adverse Reactions

In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO (n=268). Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). 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 OPDIVO plus YERVOY arm (n=313) relative to the OPDIVO arm (n=313). The most frequent (≥10%) serious adverse reactions in the OPDIVO plus YERVOY arm and the OPDIVO arm, respectively, were diarrhea (13% and 2.2%), colitis (10% and 1.9%), and pyrexia (10% and 1.0%). In Checkmate 238, serious adverse reactions occurred in 18% of patients receiving OPDIVO (n=452). Grade 3 or 4 adverse reactions occurred in 25% of OPDIVO-treated patients (n=452). The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of OPDIVO-treated patients were diarrhea and increased lipase and amylase. In Checkmate 816, serious adverse reactions occurred in 30% of patients (n=176) who were treated with OPDIVO in combination with platinum-doublet chemotherapy. Serious adverse reactions in >2% included pneumonia and vomiting. No fatal adverse reactions occurred in patients who received OPDIVO in combination with platinum-doublet chemotherapy. In Checkmate 77T, serious adverse reactions occurred in 21% of patients who received OPDIVO 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 227, serious adverse reactions occurred in 58% of patients (n=576). The most frequent (≥2%) serious adverse reactions were pneumonia, diarrhea/colitis, pneumonitis, hepatitis, pulmonary embolism, adrenal insufficiency, and hypophysitis. Fatal adverse reactions occurred in 1.7% of patients; these included events of pneumonitis (4 patients), myocarditis, acute kidney injury, shock, hyperglycemia, multi-system organ failure, and renal failure. In Checkmate 9LA, serious adverse reactions occurred in 57% of patients (n=358). The most frequent (>2%) serious adverse reactions were pneumonia, diarrhea, febrile neutropenia, anemia, acute kidney injury, musculoskeletal pain, dyspnea, pneumonitis, and respiratory failure. Fatal adverse reactions occurred in 7 (2%) patients, and included hepatic toxicity, acute renal failure, sepsis, pneumonitis, diarrhea with hypokalemia, and massive hemoptysis in the setting of thrombocytopenia. In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418).

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO 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 743, serious adverse reactions occurred in 54% of patients receiving OPDIVO plus YERVOY. The most frequent serious adverse reactions reported in ≥2% of patients were pneumonia, pyrexia, diarrhea, pneumonitis, pleural effusion, dyspnea, acute kidney injury, infusion-related reaction, musculoskeletal pain, and pulmonary embolism. Fatal adverse reactions occurred in 4 (1.3%) patients and included pneumonitis, acute heart failure, sepsis, and encephalitis. In Checkmate 214, serious adverse reactions occurred in 59% of patients receiving OPDIVO plus YERVOY (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 OPDIVO 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 OPDIVO (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 205 and 039, adverse reactions leading to discontinuation occurred in 7% and dose delays due to adverse reactions occurred in 34% of patients (n=266). Serious adverse reactions occurred in 26% of patients. The most frequent serious adverse reactions reported in ≥1% of patients were pneumonia, infusion-related reaction, pyrexia, colitis or diarrhea, pleural effusion, pneumonitis, and rash. Eleven patients died from causes other than disease progression: 3 from adverse reactions within 30 days of the last OPDIVO dose, 2 from infection 8 to 9 months after completing OPDIVO, and 6 from complications of allogeneic HSCT. In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving OPDIVO (n=236). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were pneumonia, dyspnea, respiratory failure, respiratory tract infection, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving OPDIVO (n=270). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO 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 OPDIVO (n=351). The most frequent serious adverse reaction reported in ≥2% of patients receiving OPDIVO 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 OPDIVO in combination with chemotherapy. The most frequent serious adverse reactions reporting in ≥2% of patients who received OPDIVO 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 OPDIVO in combination with chemotherapy; these included sepsis (1%). OPDIVO and/or chemotherapy were discontinued in 30% of patients and were delayed in 67% of patients for an adverse reaction. In Checkmate 8HW, serious adverse reactions occurred in 46% of patients receiving OPDIVO in combination with ipilimumab. The most frequent serious adverse reactions reported in ≥1% of patients who received OPDIVO with ipilimumab were adrenal insufficiency (2.8%), hypophysitis (2.8%), diarrhea (2.0%), abdominal pain (2.0%), small intestinal obstruction (2.0%), pneumonia (1.7%), acute kidney injury (1.4%), immune mediated enterocolitis (1.4%), pneumonitis (1.4%), colitis (1.1%), large intestinal obstruction (1.1%), and urinary tract infection (1.1%). Fatal adverse reactions occurred in 2 (0.6%) patients who received OPDIVO in combination with ipilimumab; these included myocarditis and pneumonitis (1 each). In Checkmate 8HW, serious adverse reactions occurred in 39% of patients receiving OPDIVO

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Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

alone. The most frequent serious adverse reactions reported in >1% of patients who received OPDIVO as a single agent were intestinal obstruction (2.3%), acute kidney injury (1.7%), COVID-19 (1.7%), abdominal pain (1.4%), diarrhea (1.4%), ileus (1.4%), subileus (1.4%), pulmonary embolism (1.4%), adrenal insufficiency (1.1%) and pneumonia (1.1%). Fatal adverse reactions occurring in 3 (0.9%) patients who received OPDIVO as a single agent; these included pneumonitis (n=2) and myasthenia gravis. In Checkmate 9DW, serious adverse reactions occurred in 53% of patients receiving OPDIVO with YERVOY (n=332). The most frequent non liver-related serious adverse reactions reported in ≥2% of patients who received OPDIVO with YERVOY were diarrhea/colitis (4.5%), gastrointestinal hemorrhage (3%), and rash (2.4%). Liver-related serious adverse reactions occurred in 17% of patients receiving OPDIVO with YERVOY, including Grade 3-4 events in 16% of patients. The most frequently reported all grade liver-related serious adverse reactions occurring in ≥1% of patients who received OPDIVO with YERVOY were immune-mediated hepatitis (3%), increased AST/ALT (3%), hepatic failure (2.4%), ascites (2.4%), and hepatotoxicity (1.2%). Fatal adverse reactions occurred in 12 (3.6%) patients who received OPDIVO with YERVOY; these included 4 (1.2%) patients who died due to immune-mediated or autoimmune hepatitis and 4 (1.2%) patients who died of hepatic failure. In Checkmate 040, serious adverse reactions occurred in 59% of patients receiving OPDIVO with YERVOY (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 Attraction-3, serious adverse reactions occurred in 38% of patients receiving OPDIVO (n=209). Serious adverse reactions reported in ≥2% of patients who received OPDIVO were pneumonia, esophageal fistula, interstitial lung disease, and pyrexia. The following fatal adverse reactions occurred in patients who received OPDIVO: 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 OPDIVO (n=532). A serious adverse reaction reported in ≥2% of patients who received OPDIVO was pneumonitis. A fatal reaction of myocardial infarction occurred in one patient who received OPDIVO. In Checkmate 648, serious adverse reactions occurred in 62% of patients receiving OPDIVO in combination with chemotherapy (n=310). The most frequent serious adverse reactions reported in ≥2% of patients who received OPDIVO 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, and acute kidney injury. In Checkmate 648, serious adverse reactions occurred in 69% of patients receiving OPDIVO in combination with YERVOY (n=322). The most frequent serious adverse reactions reported in ≥2% who received OPDIVO in combination with YERVOY 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 OPDIVO in combination with YERVOY; 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 OPDIVO in combination with chemotherapy (n=782). The most frequent serious adverse reactions reported in ≥2% of patients treated with OPDIVO 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 OPDIVO 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

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Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

OPDIVO (n=524). Adverse reactions which resulted in permanent discontinuation of OPDIVO 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 ≥1% of OPDIVO-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 037, the most common adverse reaction (≥20%) reported with OPDIVO (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO (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 (≥20%) adverse reactions in the OPDIVO plus YERVOY 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 067, the most common (≥20%) adverse reactions in the OPDIVO 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 238, the most common adverse reactions (≥20%) reported in OPDIVO-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 Checkmate 816, the most common (>20%) adverse reactions in the OPDIVO 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 ≥20%) in patients receiving OPDIVO 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 227, the most common (≥20%) adverse reactions were fatigue (44%), rash (34%), decreased appetite (31%), musculoskeletal pain (27%), diarrhea/colitis (26%), dyspnea (26%), cough (23%), hepatitis (21%), nausea (21%), and pruritus (21%). In Checkmate 9LA, the most common (>20%) adverse reactions were fatigue (49%), musculoskeletal pain (39%), nausea (32%), diarrhea (31%), rash (30%), decreased appetite (28%), constipation (21%), and pruritus (21%).
In Checkmate 017 and 057, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 743, the most common adverse reactions (≥20%) in patients receiving OPDIVO plus YERVOY were fatigue (43%), musculoskeletal pain (38%), rash (34%), diarrhea (32%), dyspnea (27%), nausea (24%), decreased appetite (24%), cough (23%), and pruritus (21%).
In Checkmate 214, the most common adverse reactions (≥20%) reported in patients treated with OPDIVO plus YERVOY (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 (≥20%) in patients receiving OPDIVO and cabozantinib (n=320) were diarrhea (64%), fatigue (51%), hepatotoxicity (44%), palmar-plantar erythrodysaesthesia 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 (≥20%) reported in patients receiving OPDIVO (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

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32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 205 and 039, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (n=266) were upper respiratory tract infection (44%), fatigue (39%), cough (36%), diarrhea (33%), pyrexia (29%), musculoskeletal pain (26%), rash (24%), nausea (20%) and pruritus (20%). In Checkmate 141, the most common adverse reactions (≥10%) in patients receiving OPDIVO (n=236) were cough (14%) and dyspnea (14%) at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO (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 OPDIVO (n=351) were rash (36%), fatigue (36%), diarrhea (30%), pruritus (30%), musculoskeletal pain (28%), and urinary tract infection (22%).In Checkmate 901, the most common adverse reactions (≥20%) were nausea, fatigue, musculoskeletal pain, constipation, decreased appetite, rash, vomiting, and peripheral neuropathy. In Checkmate 8HW, the most common adverse reactions reported in ≥20% of patients treated with OPDIVO in combination with ipilimumab were fatigue, diarrhea, pruritus, abdominal pain, musculoskeletal pain, and nausea. In Checkmate 8HW the most common adverse reaction reported in ≥20% of patients treated with OPDIVO as a single agent, were fatigue, diarrhea, abdominal pain, pruritus, and musculoskeletal pain. In Checkmate 9DW, the most common adverse reactions (≥20%) in patients receiving OPDIVO with YERVOY (n=332) were rash (36%), pruritus (34%), fatigue (33%), and diarrhea (25%). In Checkmate 040, the most common adverse reactions (≥20%) in patients receiving OPDIVO with YERVOY (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 Attraction-3, the most common adverse reactions (≥20%) in OPDIVO-treated patients (n=209) were rash (22%) and decreased appetite (21%). In Checkmate 577, the most common adverse reactions (≥20%) in patients receiving OPDIVO (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 (≥20%) in patients treated with OPDIVO in combination with chemotherapy (n=310) were nausea, decreased appetite, fatigue, constipation, stomatitis, diarrhea, and vomiting. In Checkmate 648, the most common adverse reactions reported in ≥20% of patients treated with OPDIVO in combination with YERVOY (n=322) were rash, fatigue, pyrexia, nausea, diarrhea, and constipation. In Checkmate 649, the most common adverse reactions (≥20%) in patients treated with OPDIVO in combination with chemotherapy (n=782) were peripheral neuropathy, nausea, fatigue, diarrhea, vomiting, decreased appetite, abdominal pain, constipation, and musculoskeletal pain. In Checkmate 76K, the most common adverse reactions (≥20%) reported with OPDIVO (n=524) were fatigue (36%), musculoskeletal pain (30%), rash (28%), diarrhea (23%) and pruritis (20%).

Surgery Related Adverse Reactions

In Checkmate 77T, 5.3% (n=12) of the OPDIVO-treated patients who received neoadjuvant treatment, did not receive surgery due to adverse reactions. The adverse reactions that led to cancellation of surgery in OPDIVO- 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).

Please see US Full Prescribing Information for OPDIVO and YERVOY.

Clinical Trials and Patient Populations

Checkmate 9DW - hepatocellular carcinoma, in combination with YERVOY; Checkmate 227—previously untreated metastatic non-small cell lung cancer, in combination with YERVOY; Checkmate 9LA–previously untreated recurrent or metastatic non-small cell lung cancer in combination with YERVOY and 2 cycles

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

of platinum-doublet chemotherapy by histology; Checkmate 649–previously untreated advanced or metastatic gastric cancer, gastroesophageal junction and esophageal adenocarcinoma; Checkmate 040–hepatocellular carcinoma, in combination with YERVOY, after prior treatment with sorafenib. ; Checkmate 577–adjuvant treatment of esophageal or gastroesophageal junction cancer; Checkmate 238–adjuvant treatment of patients with completely resected Stage III or Stage IV melanoma; Checkmate 76K–adjuvant treatment of patients 12 years of age and older with completely resected Stage IIB or Stage IIC melanoma; Checkmate 274–adjuvant treatment of urothelial carcinoma; Checkmate 275–previously treated advanced or metastatic urothelial carcinoma; 8HW: Previously Checkmate 142–MSI-H or dMMR metastatic colorectal cancer in combination with YERVOY; 8HW: Previously Checkmate 142–MSI-H or dMMR metastatic colorectal cancer, as a single agent; Attraction-3–esophageal squamous cell carcinoma; Checkmate 648—previously untreated, unresectable advanced recurrent or metastatic esophageal squamous cell carcinoma in combination with chemotherapy; Checkmate 648—previously untreated, unresectable advanced recurrent or metastatic esophageal squamous cell carcinoma combination with YERVOY; Checkmate 743–previously untreated unresectable malignant pleural mesothelioma, in combination with YERVOY; Checkmate 037–previously treated metastatic melanoma; Checkmate 066—previously untreated metastatic melanoma; Checkmate 067–previously untreated metastatic melanoma, as a single agent or in combination with YERVOY; Checkmate 017–second-line treatment of metastatic squamous non-small cell lung cancer; Checkmate 057–second-line treatment of metastatic non-squamous non-small cell lung cancer; Checkmate 816–neoadjuvant non-small cell lung cancer, in combination with platinum-doublet chemotherapy; Checkmate 77T–Neoadjuvant treatment with platinum-doublet chemotherapy for non-small cell lung cancer followed by single-agent OPDIVO as adjuvant treatment after surgery; Checkmate 901–Adult patients with unresectable or metastatic urothelial carcinoma; Checkmate 141– recurrent or metastatic squamous cell carcinoma of the head and neck; Checkmate 025–previously treated renal cell carcinoma; Checkmate 214–previously untreated renal cell carcinoma, in combination with YERVOY; Checkmate 9ER–previously untreated renal cell carcinoma, in combination with cabozantinib; Checkmate 205/039–classical Hodgkin lymphoma.

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Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy)

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

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION 120 mg + 2,000 units / mL

Important Safety Information

IMPORTANT SAFETY INFORMATION FOR OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) (cont'd)

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.

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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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

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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%). 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

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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, 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 ≥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 ≥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 ≥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%).

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Common Adverse Reactions

In Checkmate 67T, the most common adverse reactions (≥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 (≥20%) reported with intravenous nivolumab (n=268) was rash (21%). In Checkmate 066, the most common adverse reactions (≥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 (≥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 (≥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 ≥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 (≥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 (≥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 (≥20%) in patients receiving intravenous nivolumab and cabozantinib (n=320) were diarrhea (64%), fatigue (51%), hepatotoxicity (44%), palmar-plantar erythrodysaesthesia 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 (≥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 (≥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 (≥ 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 (36%), diarrhea (30%), pruritus (30%), musculoskeletal pain (28%), and urinary tract infection (22%). In Checkmate 901, the most common adverse reactions (reported in ≥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 (≥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

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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 (≥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 (≥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 (≥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 (≥20%) in intravenous nivolumab-treated patients (n=209) were rash (22%) and decreased appetite (21%). In Checkmate 577, the most common adverse reactions (≥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 (≥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%), diarrhea (29%), and vomiting (23%). In Checkmate 648, the most common adverse reactions reported in ≥20% of patients treated with intravenous nivolumab in combination with intravenous ipilimumab were rash (31%), fatigue (28%), pyrexia (23%), nausea (22%), diarrhea (22%), and constipation (20%). In Checkmate 649, the most common adverse reactions (≥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 (≥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).

Clinical Trials and Patient Populations

Checkmate 649–previously untreated advanced or metastatic gastric cancer, gastroesophageal junction and esophageal adenocarcinoma; Checkmate 577–adjuvant treatment of esophageal or gastroesophageal junction cancer; Checkmate 238–adjuvant treatment of patients with completely resected Stage III or Stage IV melanoma; Checkmate 76K–adjuvant treatment of patients 12 years of age and older with completely resected Stage IIB or Stage IIC melanoma; Checkmate 274–adjuvant treatment of urothelial carcinoma; Checkmate 275–previously treated advanced or metastatic urothelial carcinoma; Checkmate 142–MSI-H or dMMR metastatic colorectal cancer, as a single agent or in combination with YERVOY; Checkmate 142–MSI-H or dMMR metastatic colorectal cancer, as a single agent or in combination with YERVOY; Attraction-3–esophageal squamous cell carcinoma; Checkmate 648—previously untreated, unresectable advanced recurrent or metastatic esophageal squamous cell carcinoma in combination with chemotherapy; Checkmate 040–hepatocellular carcinoma, in combination with YERVOY; Checkmate 037–previously treated

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metastatic melanoma; Checkmate 066—previously untreated metastatic melanoma; Checkmate 067–previously untreated metastatic melanoma, as a single agent or in combination with YERVOY; Checkmate 017–second-line treatment of metastatic squamous non-small cell lung cancer; Checkmate 057–second-line treatment of metastatic non-squamous non-small cell lung cancer; Checkmate 816–neoadjuvant non-small cell lung cancer, in combination with platinum-doublet chemotherapy; Checkmate 77T–Neoadjuvant treatment with platinum-doublet chemotherapy for non-small cell lung cancer followed by single-agent OPDIVO as adjuvant treatment after surgery; Checkmate 901–Adult patients with unresectable or metastatic urothelial carcinoma; Checkmate 141–recurrent or metastatic squamous cell carcinoma of the head and neck; Checkmate 025–previously treated renal cell carcinoma; Checkmate 214–previously untreated renal cell carcinoma, in combination with YERVOY; Checkmate 9ER–previously untreated renal cell carcinoma, in combination with cabozantinib.

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OPDIVO® (nivolumab) INJECTION FOR INTRAVENOUS USE 10 mg/mL

OPDIVO Qvantig™ nivolumab + hyaluronidase-nvhy SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL