

ORACLE HEALTH

Updating Order PowerPlans and Regimens to Improve Access to OPDIVO Qvantig™ (nivolumab + hyaluronidase-nvhy)

Instructions and Limitations

These instructions can be used in the Oracle Health electronic health record (EHR) system only for the FDA-approved indications listed below. They will not work for other conditions, treatments, or therapeutic-related areas. The process of updating or creating new PowerPlans and Regimens is typically managed by the Health System EHR Support Team.

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54-59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.

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

Important points on how to use this tool



There are multiple indications for OPDIVO Qvantig™ covered within this tool.

There are 3 steps to update a Regimen in the Oracle Health system.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Monotherapy maintenance following nivolumab and ipilimumab combination therapy
 - c. Combination therapy
2. Add OPDIVO Qvantig package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlan(s) to the Regimen.

OPDIVO Qvantig is available as an individually packaged single-dose vial providing 600 mg of nivolumab and 10,000 units of hyaluronidase per 5 mL solution (NDC-00003-6120-01).

Please be sure the NDC is available for order in your EHR.

SELECT IMPORTANT SAFETY INFORMATION (cont.)

Severe and Fatal Immune-Mediated Adverse Reactions (cont.)

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54-59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Indications

Renal Cell Carcinoma (RCC)

- OPDIVO QVANTIG™ (nivolumab and hyaluronidase-nvhy), as monotherapy, is indicated for the first-line treatment of adult patients with intermediate- or poor-risk advanced renal cell carcinoma (RCC), following treatment with intravenous nivolumab and ipilimumab combination therapy.
 - Limitations of Use:** OPDIVO QVANTIG is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.
- OPDIVO QVANTIG, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).
- 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.

Melanoma

- OPDIVO QVANTIG, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma.
- OPDIVO QVANTIG, as monotherapy, is indicated for the treatment of adult patients with unresectable or metastatic melanoma following treatment with intravenous nivolumab and ipilimumab combination therapy.
 - Limitations of Use:** OPDIVO QVANTIG is not indicated in combination with ipilimumab for treatment of unresectable or metastatic melanoma.
- OPDIVO QVANTIG, as monotherapy, is indicated for the adjuvant treatment of adult patients with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma.

Non-Small Cell Lung Cancer (NSCLC)

- 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).
- OPDIVO QVANTIG, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) 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.
- OPDIVO QVANTIG, as monotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO QVANTIG.
 - Limitations of Use:** OPDIVO QVANTIG is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

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

Urothelial Carcinoma (UC)

- OPDIVO QVANTIG, as monotherapy, is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC.
- OPDIVO QVANTIG, in combination with cisplatin and gemcitabine, is indicated for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma (UC).
- OPDIVO QVANTIG, as monotherapy, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Esophageal Cancer

- OPDIVO QVANTIG, as monotherapy, is indicated for the adjuvant treatment of completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease in adult patients who have received neoadjuvant chemoradiotherapy (CRT).
- OPDIVO QVANTIG, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1%).
 - Limitations of Use:** OPDIVO QVANTIG is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.
- OPDIVO QVANTIG, as monotherapy, is indicated for the treatment of adult patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

- OPDIVO QVANTIG, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the treatment of adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma whose tumors express PD-L1 (≥1%).

Please note that FDA labeling states the following:

Adult patients currently receiving intravenous nivolumab as a single agent, or in combination with chemotherapy or cabozantinib, may switch to subcutaneous OPDIVO Qvantig at their next scheduled dose.

As you review this Guide, consider all treatment options and how OPDIVO Qvantig may be integrated into existing PowerPlans and Regimens.

SELECT IMPORTANT SAFETY INFORMATION


Summary of Warnings and Precautions

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



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SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Renal Cell Carcinoma (RCC)

The following pages outline the instructions to creating PowerPlans and Regimens for Advanced RCC. The instructions include options for Monotherapy, Monotherapy following Combination Therapy, and Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Monotherapy maintenance following nivolumab and ipilimumab combination therapy
 - c. Combination therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After PowerPlans have been created, add the appropriate PowerPlan(s) to the Regimen.

Advanced RCC

Monotherapy

Indication: 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.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.

Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

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

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

Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.

Combination Therapy

Indication: OPDIVO Qvantig, in combination with cabozantinib, is indicated for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC).

Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity.



Renal Cell Carcinoma (RCC)

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

Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Advanced RCC: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy for the treatment of adult patients with advanced renal cell carcinoma (RCC). who have received prior anti-angiogenic therapy. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task** > **Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units <ol style="list-style-type: none">a. Select Multiple Phaseb. Select the appropriate Plan Type: Subcutaneousc. Search for OPDIVO Qvantig 600 mg/10,000 unitsd. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3-5 mins) every 2 weeks until disease progression or unacceptable toxicitye. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attributef. Include appropriate Cycle Settings details:<ol style="list-style-type: none">i. Cycle Length: 14 daysii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity	OR	Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units <ol style="list-style-type: none">a. Select Multiple Phaseb. Select the appropriate Plan Type: Subcutaneousc. Search for OPDIVO Qvantig 1,200 mg/20,000 unitsd. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3-5 mins) every 4 weeks until disease progression or unacceptable toxicitye. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attributef. Include appropriate Cycle Settings details:<ol style="list-style-type: none">i. Cycle Length: 28 daysii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity
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5. Select **Task** > **Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54-59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Renal Cell Carcinoma (RCC)

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig™ 14-Day Cycles – RCC – Monotherapy
 - b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
 - c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
 - d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
 - e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**
- Note:** It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles – RCC – Monotherapy
 - b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
 - c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
 - d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
 - e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**
- Note:** It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Advanced RCC: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy for the first-line treatment of adult patients with intermediate or poor risk advanced renal cell carcinoma (RCC) following treatment with intravenous nivolumab and ipilimumab combination therapy. OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/ 10,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 600 mg/ 10,000 units Add the appropriate Treatment Display details: Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.) Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 14 days Number of Cycles: Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/ 20,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 1,200 mg/ 20,000 units Add appropriate Treatment Display details: Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.) Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 28 days Number of Cycles: Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Renal Cell Carcinoma (RCC)

Step 2: Creating Reference Text for Package Insert Links: Following Combination Therapy

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

Consider adding OPDIVO Qvantig™ 600 mg/10,000 units or OPDIVO Qvantig 1,200 mg/20,000 units to an existing nivolumab and ipilimumab Regimen.

Organizations may need to review and update existing nivolumab and ipilimumab Regimens when adding OPDIVO Qvantig.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 14-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of renal cell carcinoma.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked



Renal Cell Carcinoma (RCC)

Regimen 14-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.

Advanced RCC: Combination Therapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ for the first-line treatment of adult patients with advanced renal cell carcinoma (RCC) in combination with cabozantinib. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task** > **Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.



Renal Cell Carcinoma (RCC)

Name: PowerPlan 1: OPDIVO Qvantig™ 600 mg/10,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 600 mg/10,000 units**
- Add the appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle Settings** details:
 - Cycle Length: **14 days**
 - Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Cabozantinib: Until disease progression or unacceptable toxicity**

OR

Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 1,200 mg/20,000 units**
- Add appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 1,200 mg/20,000 units subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle Settings** details:
 - Cycle Length: **28 days**
 - Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Cabozantinib: Until disease progression or unacceptable toxicity**

- Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Combination Therapy

- Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
- Enter: **"Package Insert"**.
- You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
- Click **OK**, then **Save** to save the customized **Reference Text**.



Renal Cell Carcinoma (RCC)

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig™.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – RCC – Combination Therapy Cabozantinib**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/ 10,000 units subcutaneously (over ~3–5 mins) every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Cabozantinib: Until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – RCC – Combination Therapy Cabozantiinb**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/ 20,000 units subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, unacceptable toxicity, or up to 2 years. Give in combination with cabozantinib 40 mg orally once daily without food until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Cabozantinib: Until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed

Important Points

Indications

Renal Cell Carcinoma

Melanoma

Non-Small Cell Lung Cancer

Squamous Cell Carcinoma of the Head & Neck

Urothelial Carcinoma

Esophageal Cancer

Gastric Cancer

Important Safety Information



Renal Cell Carcinoma (RCC)

Regimen 14-Day Cycle (cont.):

- f. Search for **cabozantinib 40 mg** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle (cont.):

- f. Search for **cabozantinib 40 mg** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.

Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54-59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



The following pages outline the instructions to creating PowerPlans and Regimens for Melanoma. The instructions include the options for Monotherapy and Monotherapy Maintenance following Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Monotherapy maintenance following nivolumab and ipilimumab combination therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlans(s) to the Regimen.

Unresectable or Metastatic Melanoma

Monotherapy

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

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.	OR	Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.
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Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

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

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

Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.	OR	Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.
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Adjuvant Treatment of Melanoma

Monotherapy

Indication: 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.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year.	OR	Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year.
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Unresectable or Metastatic Melanoma: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy for the treatment of adult patients with unresectable or metastatic melanoma. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3-5 mins) every 2 weeks until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3-5 mins) every 4 weeks until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig™ 14-Day Cycles - Melanoma - Monotherapy - Unresectable/Metastatic
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3-5 mins) every 2 weeks until disease progression or unacceptable toxicity
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles - Melanoma - Monotherapy - Unresectable/Metastatic
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3-5 mins) every 4 weeks until disease progression or unacceptable toxicity
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Unresectable or Metastatic Melanoma: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

There are 2 approved dosing options for OPDIVO Qvantig™ as monotherapy for the treatment of adult patients with unresectable or metastatic melanoma following treatment with intravenous nivolumab and ipilimumab combination therapy. OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/ 10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/ 10,000 units d. Add the appropriate Treatment Display details: Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.) e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/ 20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/ 20,000 units d. Add appropriate Treatment Display details: Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.) e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Step 2: Creating Reference Text for Package Insert Links: Following Combination Therapy

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

Consider adding OPDIVO Qvantig™ 600 mg/10,000 units or OPDIVO Qvantig 1,200 mg/20,000 units to an existing nivolumab and ipilimumab Regimen.

Organizations may need to review and update existing nivolumab and ipilimumab Regimens when adding OPDIVO Qvantig™.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Following nivolumab and ipilimumab combination therapy, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of unresectable or metastatic melanoma.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked

Regimen 14-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Start Monotherapy Cycle 1 following nivolumab and ipilimumab combination therapy and continue monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.

Adjuvant Treatment of Melanoma: Monotherapy

There are 2 approved dosing options for OPDIVO Qvantig™ as monotherapy for the adjuvant treatment of adult patients with completely resected Stage IIB, Stage IIC, Stage III, or Stage IV melanoma. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task** > **Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.



Name: PowerPlan 1: OPDIVO Qvantig™ 600 mg/10,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 600 mg/10,000 units**
- Add the appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle** Settings details:
 - Cycle Length: **14 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year**

OR

Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 1,200 mg/20,000 units**
- Add appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle** Settings details:
 - Cycle Length: **28 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year**

- Select **Task** > **Save** Plan.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

- Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
- Enter: **"Package Insert"**.
- You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
- Click **OK**, then **Save** to save the customized **Reference Text**.



Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig™ 14-Day Cycles – Melanoma – Monotherapy – Adjuvant
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles – Melanoma – Monotherapy – Adjuvant
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Non-Small Cell Lung Cancer (NSCLC)



The following pages outline the instructions to creating PowerPlans and Regimens for Non-Small Cell Lung Cancer. The instructions include the options for Monotherapy and Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Combination Therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlans(s) to the Regimen.

Metastatic NSCLC

Monotherapy

Indication: OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO Qvantig.

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

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, or unacceptable toxicity.

Neoadjuvant Treatment of Resectable NSCLC

Combination Therapy

Indication: 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).

Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks for 3 cycles.

Neoadjuvant and Adjuvant Treatment of Resectable NSCLC

Neoadjuvant (Combination Therapy) and Adjuvant (Monotherapy)

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

Neoadjuvant Treatment: Administer OPDIVO Qvantig 900 mg/15,000 units as monotherapy subcutaneously (over ~3–5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks until disease progression or unacceptable toxicity, for up to 4 cycles.

AFTER
SURGERY
→

Adjuvant Treatment: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until following neoadjuvant therapy and surgery until disease progression, recurrence, or unacceptable toxicity, for up to 13 cycles (up to 1 year).

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Metastatic NSCLC: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy, is indicated for the treatment of adult patients with metastatic non-small cell lung cancer (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. OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.) e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.) e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find OPDIVO Qvantig in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.



Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig™ 14-Day Cycles – Metastatic NSCLC – Monotherapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles – Metastatic NSCLC – Monotherapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Neoadjuvant Treatment of Resectable NSCLC: Combination Therapy

There is 1 approved dosing option for the use of OPDIVO Qvantig™ for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) in combination with platinum-doublet chemotherapy. Organizations may choose to create a PowerPlan for this approved dose.

Step 1: Creating a New PowerPlan: Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task** > **Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Name: PowerPlan: OPDIVO Qvantig 900 mg/15,000 units

- a. Select **Multiple Phase**
- b. Select the appropriate **Plan Type: Subcutaneous**
- c. Search for **OPDIVO Qvantig 900 mg/15,000 units**
- d. Add the appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3-5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks for 3 cycles**
- e. Set the **Scheduling Component** to **Injection 3-5 Minutes** and select the **Scheduled Phases** attribute
- f. Include appropriate **Cycle Settings** details:
 - i. Cycle Length: **21 days**
 - ii. Number of Cycles: **3 combination cycles on the same day as platinum-doublet chemotherapy**

5. Select **Task** > **Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Combination Therapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Non-Small Cell Lung Cancer (NSCLC)

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

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig™.

Regimen 21-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 21-Day Cycles – NSCLC – Neoadjuvant – Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan: OPDIVO Qvantig 900 mg/15,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks for 3 cycles**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **21 days**
 - ii. Number of Cycles: **3 combination cycles on the same day as platinum-doublet chemotherapy**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Search for **platinum-doublet chemotherapy** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.

Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Neoadjuvant and Adjuvant Treatment of Resectable NSCLC: Combination Therapy

There is 1 approved dosing option for neoadjuvant therapy and 1 approved dosing option for adjuvant therapy for the use of OPDIVO Qvantig™, in combination with platinum-doublet chemotherapy, is indicated for the neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent OPDIVO Qvantig as monotherapy in the adjuvant setting after surgical resection.

Step 1: Creating a New PowerPlan: Neoadjuvant (Combination Therapy) and Adjuvant (Monotherapy)

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: Neoadjuvant Therapy PowerPlan and Adjuvant Therapy PowerPlan should be built to be dependent upon each other.

Neoadjuvant Therapy PowerPlan: OPDIVO Qvantig 900 mg/15,000 units		Adjuvant Therapy PowerPlan: OPDIVO Qvantig 1,200 mg/20,000 units
<ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 900 mg/15,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks until disease progression or unacceptable toxicity, for up to 4 cycles e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 21 days ii. Number of Cycles: 4 combination cycles one the same day as platinum-doublet chemotherapy 	<p>AFTER SURGERY →</p>	<ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Following neoadjuvant therapy and surgery, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, recurrence, or unacceptable toxicity, for up to 13 cycles (up to 1 year) e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Following neoadjuvant therapy and surgery, start monotherapy cycles 5-17 (up to 13 cycles ~1 year)

5. Select **Task > Save Plan**.



Step 2: Creating Reference Text for Package Insert Links: Neoadjuvant (Combination Therapy) and Adjuvant (Monotherapy)

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig.

Neoadjuvant Regimen 21-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 21-Day Cycles - NSCLC - Neoadjuvant - Combination Therapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **Neoadjuvant Therapy PowerPlan: OPDIVO Qvantig 900 mg/ 15,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 900 mg/ 15,000 units subcutaneously (over ~3-5 mins) with platinum-doublet chemotherapy on the same day every 3 weeks until disease progression or unacceptable toxicity, for up to 4 cycles**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked

AFTER
SURGERY
→

Adjuvant Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example:
OPDIVO Qvantig 28-Day Cycles - NSCLC - Adjuvant following neoadjuvant and surgery - Monotherapy
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **Adjuvant Therapy PowerPlan: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Following neoadjuvant therapy and surgery, administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3-5 mins) every 4 weeks until disease progression, recurrence, or unacceptable toxicity, for up to 13 cycles (up to 1 year)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked



Non-Small Cell Lung Cancer (NSCLC)

Neoadjuvant Regimen 21-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **21 days**
 - ii. Number of Cycles: **4 combination cycles one the same day as platinum-doublet chemotherapy**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Search for **platinum-doublet chemotherapy** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

AFTER
SURGERY
→

Adjuvant Regimen 28-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Following neoadjuvant therapy and surgery, start monotherapy cycles 5-17 (up to 13 cycles ~1 year)**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Squamous Cell Carcinoma of the Head and Neck (SCCHN)

The following pages outline the instructions to creating PowerPlans and Regimens for Squamous Cell Carcinoma of the Head and Neck (SCCHN). The instructions include the options for Monotherapy. There are 3 steps to update a Regimen in the Oracle Health system for the indication below.

1. Create PowerPlans for:
 - a. Monotherapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlan(s) to the Regimen.

Squamous Cell Carcinoma of the Head and Neck (SCCHN): Monotherapy

Indication: 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.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.

There are 2 approved dosing options for the use of OPDIVO Qvantig as monotherapy 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. Organizations may choose to create a PowerPlan for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.



Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Name: PowerPlan 1: OPDIVO Qvantig™ 600 mg/10,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 600 mg/10,000 units**
- Add the appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle Settings** details:
 - Cycle Length: **14 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

OR

Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units

- Select **Multiple Phase**
- Select the appropriate **Plan Type: Subcutaneous**
- Search for **OPDIVO Qvantig 1,200 mg/20,000 units**
- Add appropriate **Treatment Display** details: **Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity**
- Set the **Scheduling Component** to **Injection 3–5 Minutes** and select the **Scheduled Phases** attribute
- Include appropriate **Cycle Settings** details:
 - Cycle Length: **28 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

- Select **Task** > **Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

- Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
- Enter: **"Package Insert"**.
- You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
- Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

- Login to **regimenbuilder**.
- Click the Green Calendar **Create New Regimen** icon.



Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Regimen 14-Day Cycle:

- Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig™ 14-Day Cycles – SCCHN – Monotherapy**
- Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- Update the **Regimen Description**:
 - Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity
 - Extend Regimen is Checked
 - Add Plan is Checked
- Include appropriate **Cycle** and **Day** details:
 - Cycle Length: **14 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- Add any additional **Orders** such as:
 - Patient education
 - Supportive care medications
 - NCCN parameters
 - Appointment requests

OR

Regimen 28-Day Cycle:

- Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – SCCHN – Monotherapy**
- Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- Update the **Regimen Description**:
 - Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity
 - Extend Regimen is Checked
 - Add Plan is Checked
- Include appropriate **Cycle** and **Day** details:
 - Cycle Length: **28 days**
 - Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- Add any additional **Orders** such as: i.
 - Patient education
 - Supportive care medications
 - NCCN parameters
 - Appointment requests

- Select the **Save** button.



Urothelial Carcinoma (UC)

The following pages outline the instructions to creating PowerPlans and Regimens for Urothelial Carcinoma. The instructions include the options for Monotherapy and Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Combination Therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlans(s) to the Regimen.

Locally Advanced or Metastatic UC

Monotherapy

Indication: OPDIVO Qvantig, as monotherapy, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression, or unacceptable toxicity.

Adjuvant Treatment of UC

Monotherapy

Indication: 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.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

First-line Unresectable or Metastatic UC

Combination Therapy

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

Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) in combination with cisplatin and gemcitabine on the same day every 3 weeks for up to 6 cycles.

AND

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks after completing up to 6 cycles of combination therapy until disease progression, unacceptable toxicity, or up to 2 years from first dose.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks after completing up to 6 cycles of combination therapy until disease progression, unacceptable toxicity, or up to 2 years from first dose.



Locally Advanced or Metastatic UC: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3-5 mins) every 2 weeks until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3-5 mins) every 4 weeks until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3-5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Urothelial Carcinoma (UC)

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s), or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – Monotherapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Adjuvant Treatment of UC: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year
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5. Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.



Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s), or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:	OR	Regimen 28-Day Cycle:
<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig™ 14-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year ii. Extend Regimen is Checked iii. Add Plan is Checked e. Include appropriate Cycle and Day details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year iii. Select Click here to add Regimen Offsets to insert appropriate amount of time between Cycles <p><i>Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.</i></p> <ol style="list-style-type: none"> f. Add any additional Orders such as: <ol style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests 		<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year ii. Extend Regimen is Checked iii. Add Plan is Checked e. Include appropriate Cycle and Day details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year iii. Select Click here to add Regimen Offsets to insert appropriate amount of time between Cycles <p><i>Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.</i></p> <ol style="list-style-type: none"> f. Add any additional Orders such as: <ol style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests

3. Select the **Save** button.



First-line Unresectable or Metastatic UC: Combination Therapy

There is 1 fixed dose followed by 2 approved dosing options for the use of OPDIVO Qvantig™, in combination with cisplatin and gemcitabine, for the first-line treatment of adult patients with unresectable or metastatic UC. Organizations may choose to create PowerPlans for one or all of the approved doses.

Step 1: Creating a New PowerPlan: Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan OPDIVO Qvantig 900 mg/15,000 units should be built for independent utilization with PowerPlan OPDIVO Qvantig 600 mg/10,000 units or PowerPlan OPDIVO Qvantig 1,200/20,000 units per organizational standards.

<p>Name: PowerPlan: OPDIVO Qvantig 900 mg/15,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 900 mg/15,000 units Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) in combination with cisplatin and gemcitabine on the same day every 3 weeks for up to 6 cycles Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 21 days Number of Cycles: Complete Combination Cycle 1 and continue combination cycles for up to 6 cycles on the same day as cisplatin and gemcitabine therapy 	AND	<p>Name: PowerPlan: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 600 mg/10,000 units Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks after completing up to 6 cycles of combination therapy until disease progression, unacceptable toxicity, or up to 2 years from 1st dose Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 14 days Number of Cycles: Complete up to 6 cycles of combination therapy and start monotherapy cycles until disease progression, unacceptable toxicity, or up to 2 years from 1st dose 	OR	<p>Name: PowerPlan: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 1,200 mg/20,000 units Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks after completing up to 6 cycles of combination therapy until disease progression, unacceptable toxicity, or up to 2 years from 1st dose Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 28 days Number of Cycles: Complete up to 6 cycles of combination therapy and start monotherapy cycles until disease progression, unacceptable toxicity, or up to 2 years from 1st dose
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5. Select **Task > Save Plan**.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Step 2: Creating Reference Text for Package Insert Links: Following Combination Therapy

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig™.

Regimen 21-Day Cycle:		Regimen 14-Day Cycle:		Regimen 28-Day Cycle:
<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig 21-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Combination Therapy b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan: OPDIVO Qvantig 900 mg/15,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) in combination with cisplatin and gemcitabine on the same day every 3 weeks for up to 6 cycles ii. Extend Regimen is Checked iii. Add Plan is Checked 	AND	<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Following Combination Therapy b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan: OPDIVO Qvantig 600 mg/10,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks after completing combination therapy until disease progression, unacceptable toxicity, or up to 2 years from 1st dose ii. Extend Regimen is Checked iii. Add Plan is Checked 	OR	<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Following Combination Therapy b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan: OPDIVO Qvantig 1,200 mg/20,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks after completing combination therapy until disease progression, unacceptable toxicity, or up to 2 years from 1st dose ii. Extend Regimen is Checked iii. Add Plan is Checked



Urothelial Carcinoma (UC)

Regimen 21-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **21 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles for up to 6 cycles on the same day as cisplatin and gemcitabine therapy**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Search for **cisplatin** and add to the **Regimen**
- g. Search for **gemcitabine** and add to the **Regimen**
- h. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

AND

Regimen 14-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete up to 6 cycles of combination therapy and start monotherapy cycles until disease progression, unacceptable toxicity, or up to 2 years from 1st dose**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete up to 6 cycles of combination therapy and start monotherapy cycles until disease progression, unacceptable toxicity, or up to 2 years from 1st dose**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



The following pages outline the instructions to creating PowerPlans and Regimens for Esophageal Cancer. The instructions include the options for Monotherapy and Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Monotherapy
 - b. Combination Therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlans(s) to the Regimen.

Adjuvant Treatment of Resected Esophageal or Gastroesophageal Junction Cancer

Monotherapy

Indication: 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).

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year.

Esophageal Squamous Cell Carcinoma (ESCC)

Combination Therapy

Indication: 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 ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.

Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units subcutaneously (over ~3–5 mins) every 4 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years.

Monotherapy

Indication: 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.

Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity.



Adjuvant Treatment of Resected Esophageal or Gastroesophageal Junction Cancer: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy 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). Organizations may choose to create PowerPlans for one or both of the approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task** > **Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year
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5. Select **Task** > **Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.



Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon.

Regimen 14-Day Cycle:	OR	Regimen 28-Day Cycle:
<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig™ 14-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 600 mg/ 10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease recurrence or unacceptable toxicity for up to 1 year ii. Extend Regimen is Checked iii. Add Plan is Checked e. Include appropriate Cycle and Day details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year iii. Select Click here to add Regimen Offsets to insert appropriate amount of time between Cycles <p><i>Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.</i></p> <ol style="list-style-type: none"> f. Add any additional Orders such as: <ol style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests 		<ol style="list-style-type: none"> a. Name per organizational naming and numbering standard, for example: OPDIVO Qvantig 28-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy b. Select OK and the shell of the PowerPlan created in Step 1 loads in the background c. Search for PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units d. Update the Regimen Description: <ol style="list-style-type: none"> i. Administer OPDIVO Qvantig 1,200 mg/ 20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year ii. Extend Regimen is Checked iii. Add Plan is Checked e. Include appropriate Cycle and Day details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year iii. Select Click here to add Regimen Offsets to insert appropriate amount of time between Cycles <p><i>Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.</i></p> <ol style="list-style-type: none"> f. Add any additional Orders such as: <ol style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests

3. Select the **Save** button.



Esophageal Squamous Cell Carcinoma: Combination Therapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1%) in combination with fluoropyrimidine- and platinum-containing chemotherapy. OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC. Organizations may choose to create PowerPlans for one or both of these approved doses.

Step 1: Creating a New PowerPlan: Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 600 mg/10,000 units Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.) Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 14 days Number of Cycles: Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> Select Multiple Phase Select the appropriate Plan Type: Subcutaneous Search for OPDIVO Qvantig 1,200 mg/20,000 units Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units subcutaneously (over ~3–5 mins) every 4 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.) Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute Include appropriate Cycle Settings details: <ol style="list-style-type: none"> Cycle Length: 28 days Number of Cycles: Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years
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5. Select **Task > Save Plan**.



Step 2: Creating Reference Text for Package Insert Links: Combination Therapy

1. Find **OPDIVO Qvantig™** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – ESCC – Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) every 2 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – ESCC – Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/20,000 units subcutaneously (over ~3–5 mins) every 4 weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy until disease progression, unacceptable toxicity, or up to 2 years (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of patients with unresectable advanced or metastatic ESCC.)**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked



Regimen 14-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

OR

Regimen 28-Day Cycle (cont.):

- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

- f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** and add to the **Regimen**
- g. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

3. Select the **Save** button.



Esophageal Squamous Cell Carcinoma: Monotherapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ as monotherapy for the treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC after prior fluoropyrimidine- and platinum-based chemotherapy. Organizations may choose to create Regimens for one or both of the approved doses.

Step 1: Creating a New PowerPlan: Monotherapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity after completing fluoropyrimidine- and platinum-based chemotherapy e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 1,200 mg/20,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity after completing fluoropyrimidine- and platinum-based chemotherapy e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 28 days ii. Number of Cycles: Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Monotherapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **"Package Insert"**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.



Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a new Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig™.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig™ 14-Day Cycles – ESCC – Monotherapy After Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/10,000 units as monotherapy subcutaneously (over ~3–5 mins) every 2 weeks until disease progression or unacceptable toxicity after completing fluoropyrimidine- and platinum-based chemotherapy**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

OR

Regimen 28-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – ESCC – Monotherapy After Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 1,200 mg/20,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 1,200 mg/20,000 units as monotherapy subcutaneously (over ~3–5 mins) every 4 weeks until disease progression or unacceptable toxicity after completing fluoropyrimidine- and platinum-based chemotherapy**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **28 days**
 - ii. Number of Cycles: **Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**
- f. Add any additional **Orders** such as:
 - i. Patient education
 - ii. Supportive care medications
 - iii. NCCN parameters
 - iv. Appointment requests

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

3. Select the **Save** button.



Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma



The following pages outline the instructions to creating PowerPlans and Regimens for Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma. The instructions include the options for Combination Therapy. There are 3 steps to update a Regimen in the Oracle Health system for each of the indications below.

1. Create PowerPlans for:
 - a. Combination Therapy
2. Add OPDIVO Qvantig™ package insert links as Reference Text.
3. After the PowerPlans have been created, add the appropriate PowerPlans to the Regimen.

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma: Combination Therapy

Indication: 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 ($\geq 1\%$).

Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity.

OR

Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity.

There are 2 approved dosing options for the use of OPDIVO Qvantig for the treatment of adult patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy. Organizations may choose to create Regimens for one or both of the approved doses.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Important Points

Indications

Renal Cell Carcinoma

Melanoma

Non-Small Cell Lung Cancer

Squamous Cell Carcinoma of the Head & Neck

Urothelial Carcinoma

Esophageal Cancer

Gastric Cancer

Important Safety Information

Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma



Important Points

Indications

Renal Cell Carcinoma

Melanoma

Non-Small Cell Lung Cancer

Squamous Cell Carcinoma of the Head & Neck

Urothelial Carcinoma

Esophageal Cancer

Gastric Cancer

Important Safety Information

Step 1: Creating a New PowerPlan: Combination Therapy

1. Login to **DCPTOOLS**.
2. Navigate to the **PowerPlan Tool**.
3. Click **Task > Open Plan** or **Create New Plan** icon.
4. Add a user-friendly **Name** to make it easy for users to determine which PowerPlan to use. The **Names** shown in the PowerPlan builds below are provided as examples.

Note: PowerPlan 1 and PowerPlan 2 should be built for independent utilization per organizational standards.

<p>Name: PowerPlan 1: OPDIVO Qvantig™ 600 mg/10,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 600 mg/10,000 units d. Add the appropriate Treatment Display details: Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 14 days ii. Number of Cycles: Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity 	OR	<p>Name: PowerPlan 2: OPDIVO Qvantig 900 mg/15,000 units</p> <ol style="list-style-type: none"> a. Select Multiple Phase b. Select the appropriate Plan Type: Subcutaneous c. Search for OPDIVO Qvantig 900 mg/15,000 units d. Add appropriate Treatment Display details: Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity e. Set the Scheduling Component to Injection 3–5 Minutes and select the Scheduled Phases attribute f. Include appropriate Cycle Settings details: <ol style="list-style-type: none"> i. Cycle Length: 21 days ii. Number of Cycles: Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity
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5. Select **Task > Save Plan**.

Step 2: Creating Reference Text for Package Insert Links: Combination Therapy

1. Find **OPDIVO Qvantig** in the medication database and select the **Reference Text** tab. Click **Customize** to launch the **Edit Interaction** window.
2. Enter: **“Package Insert”**.
3. You may also add the following URL: https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf.
4. Click **OK**, then **Save** to save the customized **Reference Text**.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

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

Step 3: Adding PowerPlans to a Regimen

Once the **PowerPlans** have been created, they may be added to an existing Regimen(s) or a new Regimen may be created. The following steps show how to add the PowerPlans created in **Step 1** to a Regimen.

1. Login to **regimenbuilder**.
2. Click the Green Calendar **Create New Regimen** icon or search for an existing **Regimen**.

Organizations may need to review and update existing Regimens when adding OPDIVO Qvantig™.

Regimen 14-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – GC/GEJC/EAC – Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 1: OPDIVO Qvantig 600 mg/10,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 600 mg/10,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 2 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **14 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

OR

Regimen 21-Day Cycle:

- a. Name per organizational naming and numbering standard, for example: **OPDIVO Qvantig 21-Day Cycles – GC/GEJC/EAC – Combination Therapy**
- b. Select **OK** and the shell of the **PowerPlan** created in **Step 1** loads in the background
- c. Search for **PowerPlan 2: OPDIVO Qvantig 900 mg/15,000 units**
- d. Update the **Regimen Description**:
 - i. **Administer OPDIVO Qvantig 900 mg/15,000 units subcutaneously (over ~3–5 mins) with fluoropyrimidine- and platinum-containing chemotherapy every 3 weeks until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity**
 - ii. **Extend Regimen** is Checked
 - iii. **Add Plan** is Checked
- e. Include appropriate **Cycle** and **Day** details:
 - i. Cycle Length: **21 days**
 - ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles until disease progression, unacceptable toxicity, or up to 2 years. Chemotherapy: Until disease progression or unacceptable toxicity**
 - iii. Select **Click here** to add **Regimen Offsets** to insert appropriate amount of time between **Cycles**

Note: It is recommended to not create Regimens with more than 6 months' worth of Treatment unless otherwise needed.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma

Regimen 14-Day Cycle (cont.): <ul style="list-style-type: none"> f. Search for fluoropyrimidine- and platinum-containing chemotherapy and add to the Regimen g. Add any additional Orders such as: <ul style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests 	OR	Regimen 21-Day Cycle (cont.): <ul style="list-style-type: none"> f. Search for fluoropyrimidine- and platinum-containing chemotherapy and add to the Regimen g. Add any additional Orders such as: <ul style="list-style-type: none"> i. Patient education ii. Supportive care medications iii. NCCN parameters iv. Appointment requests
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3. Select the **Save** button.



Notes:

- The organization shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in the organization's EHR system. The organization has sole and complete responsibility for ensuring the accuracy of the organization's EHR system at all times
- The organization is responsible for performing its own clinical review of these instructions and any other materials provided by Bristol-Myers Squibb (BMS)
- Capabilities, functionality, and setup (customization) for each individual EHR system vary. BMS shall not be responsible for revising the implementation instructions it provides to any organization in the event that the organization modifies or changes its software or the configuration of its EHR system after such time as the implementation instructions have been initially provided by BMS
- While EHRs may assist HCPs in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be decided by an HCP in consultation with the patient, after a review of the patient's records to determine eligibility, and BMS shall have no liability thereto
- The instructions have not been designed to meet and are not tools and/or solutions for meeting Meaningful Use and/or any other quality/accreditation requirement
- BMS will make every effort to update materials provided by BMS in a timely manner, but the customer is ultimately responsible for ensuring the accuracy of the EHR system
- Any clinical decision to prescribe OPDIVO Qvantig™ is based upon the best interests of the patient and is unrelated to the services provided by BMS
- The instructions and materials provided by BMS are based on OPDIVO Qvantig FDA-approved indications. BMS makes no representation as to their applicability for use outside of OPDIVO Qvantig approved indications
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of BMS and/or its affiliates



Important Safety Information



Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

Important
Safety
Information

Severe and Fatal Immune-Mediated Adverse Reactions

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

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

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

Immune-Mediated Pneumonitis

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

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

Immune-Mediated Colitis

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

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

Immune-Mediated Hepatitis and Hepatotoxicity

OPDIVO QVANTIG can cause immune-mediated hepatitis.

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

Immune-Mediated Endocrinopathies

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54–59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Important Safety Information



Important
Points

Indications

Renal Cell
Carcinoma

Melanoma

Non-Small Cell
Lung Cancer

Squamous Cell
Carcinoma of the
Head & Neck

Urothelial
Carcinoma

Esophageal
Cancer

Gastric
Cancer

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Immune-Mediated Endocrinopathies (cont'd)

Adrenal insufficiency occurred in 2% (5/247) of patients receiving OPDIVO QVANTIG™ (nivolumab and hyaluronidase-nvhy), 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 palsy, 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.

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.

Please see additional Important Safety Information for OPDIVO Qvantig on pages [54-59](#) and [U.S. Full Prescribing Information](#) for OPDIVO Qvantig.



Important Safety Information



Embryo-Fetal Toxicity

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

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

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

Lactation

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

Serious Adverse Reactions

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

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

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Important Safety Information

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

Serious Adverse Reactions (cont'd)

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 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

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Serious Adverse Reactions (cont'd)

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%).

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 erythrodysesthesia syndrome (40%), stomatitis (37%), rash (36%), hypertension (36%), hypothyroidism (34%), musculoskeletal pain (33%), decreased appetite (28%), nausea (27%), dysgeusia (24%), abdominal pain (22%), cough (20%) and upper respiratory tract infection (20%). In Checkmate 025, the most common adverse reactions (≥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 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%),

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Common Adverse Reactions (cont'd)

and abdominal pain (21% vs 23%). The most common immune-mediated adverse reactions were rash (16%), diarrhea/colitis (6%), and hepatitis (3%). In Attraction-3, the most common adverse reactions ($\geq 20\%$) in intravenous nivolumab-treated patients (n=209) were rash (22%) and decreased appetite (21%). In Checkmate 577, the most common adverse reactions ($\geq 20\%$) in patients receiving intravenous nivolumab (n=532) were fatigue (34%), diarrhea (29%), nausea (23%), rash (21%), musculoskeletal pain (21%), and cough (20%). In Checkmate 648, the most common adverse reactions ($\geq 20\%$) in patients treated with intravenous nivolumab in combination with chemotherapy (n=310) were nausea (65%), decreased appetite (51%), fatigue (47%), constipation (44%), stomatitis (44%), diarrhea (29%), and vomiting (23%). In Checkmate 648, the most common adverse reactions reported in $\geq 20\%$ of patients treated with intravenous nivolumab in combination with intravenous ipilimumab were rash (31%), fatigue (28%), pyrexia (23%), nausea (22%), diarrhea (22%), and constipation (20%). In Checkmate 649, the most common adverse reactions ($\geq 20\%$) in patients treated with intravenous nivolumab in combination with chemotherapy (n=782) were peripheral neuropathy (53%), nausea (48%), fatigue (44%), diarrhea (39%), vomiting (31%), decreased appetite (29%), abdominal pain (27%), constipation (25%), and musculoskeletal pain (20%). In Checkmate 76K, the most common adverse reactions ($\geq 20\%$) reported with intravenous nivolumab (n=524) were fatigue (36%), musculoskeletal pain (30%), rash (28%), diarrhea (23%) and pruritus (20%).

Surgery Related Adverse Reactions

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

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; 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 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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References:

1. OPDIVO Qvantig™ (nivolumab + hyaluronidase-nvhy) package insert. Princeton, NJ: Bristol-Myers Squibb Company; 2025.

