OncoEMR®

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

Instructions and Limitations

These instructions can be used in the OncoEMR 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 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 36–41 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

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

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

There are 3 Regimens you may want to consider creating or updating in OncoEMR.

Create or update Regimens for:

1. Monotherapy
2. Monotherapy maintenance following nivolumab and ipilimumab combination therapy
3. Combination therapy

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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Indications

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

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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Table of Contents

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

The following instructions show how to create Regimens for all indications for OPDIVO Qvantig™. Use the hyperlinks in the Table of Contents below or the tabs on each page to navigate. The ⌂ will bring you back to this page.

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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Renal Cell Carcinoma (RCC)

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

The following pages outline the instructions to creating or updating Regimens for Advanced RCC in OncoEMR. The instructions include the options for Monotherapy, Monotherapy following Combination Therapy, and Combination Therapy.

Create or Update Regimens for:

a. Monotherapy
b. Monotherapy maintenance following nivolumab and ipilimumab combination therapy
c. Combination therapy

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 intravenous 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.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 Regimens for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – RCC – Monotherapy and Regimen OPDIVO Qvantig 28-Day Cycles – RCC – Monotherapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – RCC – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – RCC – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimens for one or both of these approved doses.

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.

Creating a New Regimen: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy and Regimen OPDIVO Qvantig 28-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – RCC – Post nivolumab and ipilimumab combination therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

d. Search for **OPDIVO Qvantig™ 600 mg/10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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.):

d. Search for **OPDIVO Qvantig 1,200 mg/20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimens for one or both of these approved doses.

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

Creating a New Regimen: Combination Therapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – RCC – Combination Therapy Cabozantinib and Regimen OPDIVO Qvantig 28-Day Cycles – RCC – Combination Therapy Cabozantinib should be built for independent utilization per organizational standards.*

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Renal Cell Carcinoma (RCC)

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

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig™ 14-Day Cycles – RCC – Combination Therapy Cabozantinib**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **cabozantinib 40 mg** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – RCC – Combination Therapy Cabozantinib**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **cabozantinib 40 mg** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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Melanoma

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

The following pages outline the instructions to creating Regimens for Melanoma in OncoEMR. The instructions include the options for Monotherapy and Monotherapy Maintenance following Combination Therapy.

Create or Update Regimens for:

a. Monotherapy
b. Monotherapy maintenance following nivolumab and ipilimumab combination therapy

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.

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.

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.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 Regimens for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Melanoma – Monotherapy – Unresectable/Metastatic and Regimen OPDIVO Qvantig 28-Day Cycles – Melanoma – Monotherapy – Unresectable/Metastatic should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Melanoma – Monotherapy – Unresectable/Metastatic**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Melanoma – Monotherapy – Unresectable/Metastatic**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimens for one or both of the approved doses.

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.

Creating a New Regimen: Monotherapy Maintenance Following Nivolumab and Ipilimumab Combination Therapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy – Unresectable/Metastatic and Regimen OPDIVO Qvantig 28-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy – Unresectable/Metastatic should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:	OR	**Regimen 28-Day Cycle:**
a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy – Unresectable/Metastatic** b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**		a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Melanoma – Post nivolumab and ipilimumab combination therapy – Unresectable/Metastatic** b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig™ 600 mg/10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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.):

c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimens for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig™ 14-Day Cycles – Melanoma – Monotherapy – Adjuvant and Regimen OPDIVO Qvantig 28-Day Cycles – Melanoma – Monotherapy – Adjuvant should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Melanoma – Monotherapy – Adjuvant**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Melanoma – Monotherapy – Adjuvant**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Non-Small Cell Lung Cancer (NSCLC)

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

The following pages outline the instructions to creating or updating Regimens for Non-Small Cell Lung Cancer (NSCLC) in OncoEMR. The instructions include the options for Monotherapy and Combination Therapy.

Create or Update Regimens for:

a. Monotherapy
b. Combination Therapy

Metastatic NSCLC

Monotherapy

Indication: OPDIVO Qvantig™, 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 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 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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 Regimens for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Metastatic NSCLC – Monotherapy and Regimen OPDIVO Qvantig 28-Day Cycles - Metastatic NSCLC - Monotherapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Metastatic NSCLC – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** details: **Administer OPDIVO Qvantig 600 mg/ 10,000 units subcutaneously (over 3–5 mins) every as monotherapy 2 weeks until disease progression or unacceptable toxicity (OPDIVO Qvantig is not indicated in combination with ipilimumab for the treatment of metastatic NSCLC.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Metastatic NSCLC – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

h. 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.):

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

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimen for this approved dose.

Creating a New Regimen: Combination Therapy

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

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

Regimen 21-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 21-Day Cycles – NSCLC – Neoadjuvant – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **21 days**
   ii. Number of Cycles: **3 combination cycles on the same day as platinum-doublet chemotherapy**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 900 mg/15,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **platinum-doublet chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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.

Creating a New Regimen: Combination Therapy

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

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *OPDIVO Qvantig 21-Day Cycles – NSCLC – Neoadjuvant – Combination Therapy Regimen and OPDIVO Qvantig 28-Day Cycles – Adjuvant following neoadjuvant and surgery – Monotherapy Regimen should be built to be dependent upon each other.*

Neoadjuvant Therapy Regimen 21-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 21-Day Cycles – NSCLC – Neoadjuvant – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **21 days**
   ii. Number of Cycles: **4 combination cycles on the same day as platinum-doublet chemotherapy**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 900 mg/ 15,000 units** by clicking **Add Drug**

AFTER SURGERY →

Adjuvant Therapy Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Adjuvant following neoadjuvant and surgery – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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)**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Neoadjuvant Therapy Regimen 21-Day Cycle (cont):

e. Select **Edit** to add **Description** 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**
f. Search for **platinum-doublet chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

AFTER SURGERY →

Adjuvant Therapy Regimen 28-Day Cycle (cont.):

e. Select **Edit** to add **Description** 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)**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

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

The following pages outline the instructions to creating or updating Regimens for Squamous Cell Carcinoma of the Head and Neck (SCCHN) in OncoEMR. The instructions include the options for Monotherapy.

Create or Update Regimens for:

a. Monotherapy

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 Regimen for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – SCCHN – Monotherapy and Regimen OPDIVO Qvantig 28-Day Cycles – SCCHN – Monotherapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – SCCHN – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – SCCHN – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Squamous Cell Carcinoma of the Head and Neck (SCCHN)

Regimen 14-Day Cycle (cont.):

d. Search for **OPDIVO Qvantig™ 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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.):

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Urothelial Carcinoma (UC)

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

The following pages outline the instructions to creating or updating Regimens for Urothelial Carcinoma in OncoEMR. The instructions include the options for Monotherapy and Combination Therapy.

Create or Update Regimens for:

a. Monotherapy
b. Combination Therapy

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 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.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 a Regimen for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – Monotherapy and Regimen OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 Regimens for one or both of these approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant and Regimen OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – Monotherapy – Adjuvant**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

First-line Unresectable or Metastatic UC: Combination Therapy

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

Creating a New Regimen: Combination Therapy

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

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 21-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Combination Therapy should be built for independent utilization with Regimen OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Post Combination Therapy or Regimen OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Post Combination Therapy per organizational standards.*

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Urothelial Carcinoma (UC)

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

Regimen 21-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig™ 21-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **21 days**
   ii. Number of Cycles: **Complete Combination Cycle 1 and continue combination cycles up to 6 cycles on the same day as cisplatin and gemcitabine therapy**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 900 mg/15,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **cisplatin** by clicking Add Drug
g. Search for **gemcitabine** by clicking Add Drug

AND

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Post Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** details: **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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Urothelial Carcinoma – First-line Unresectable/Metastatic – Post Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** details: **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 since 1st dose**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 21-Day Cycle (cont.): **h.** Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf **i.** Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened **j.** 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.):** **h.** 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.):** **h.** Add any additional **Orders** such as: **i.** Patient education **ii.** Supportive care medications **iii.** NCCN parameters **iv.** Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Esophageal Cancer

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

The following pages outline the instructions to creating or updating Regimens for Esophageal Cancer in OncoEMR. The instructions include the options for Monotherapy and Combination Therapy.

Create or Update Regimens for:

a. Monotherapy
b. Combination Therapy

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.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 Regimens for one or both of the approved doses.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy and Regimen OPDIVO Qvantig 28-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: 1**4 days**
   ii. Number of Cycles: **Complete Cycle 1 and continue cycles until disease recurrence or unacceptable toxicity for up to 1 year**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – Esophageal or GEJ Cancer Adjuvant – Monotherapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Esophageal Squamous Cell Carcinoma: Combination Therapy

There are 2 approved dosing options for the use of OPDIVO Qvantig™ for the 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 Regimens for one or both of these approved doses.

Creating a New Regimen: Combination Therapy

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

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – ESCC – Combination Therapy and Regimen OPDIVO Qvantig 28-Day Cycles – ESCC – Combination Therapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – ESCC – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**

OR

Regimen 28-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – ESCC – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Regimen 14-Day Cycle (cont.):

c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig™ 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. 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.):

c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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.)**
f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

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.

Creating a New Regimen: Monotherapy

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

2. Click **New Regimen**.
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig™ 14-Day Cycles – ESCC – Monotherapy After Combination Therapy and Regimen OPDIVO Qvantig 28-Day Cycles – ESCC – Monotherapy After Combination Therapy should be built for independent utilization per organizational standards.*

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 14-Day Cycles – ESCC – Monotherapy After Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **14 days**
   ii. Number of Cycles: **Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. 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. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 28-Day Cycles – ESCC – Monotherapy After Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   i. Cycle Length: **28 days**
   ii. Number of Cycles: **Complete Combination Cycles and start new monotherapy cycles until disease progression or unacceptable toxicity**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 1,200 mg/ 20,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
g. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
h. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 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

The following pages outline the instructions to creating or updating Regimens for Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma in OncoEMR. The instructions include the options for Combination Therapy.

Create or Update Regimens for:

a. Combination Therapy

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 (≥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.

Creating a New Regimen: Combination Therapy

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

1. In the **Customize** section, navigate to the **Regimens List** under the **Regimens** section.
2. Click **New Regimen** or search for an existing **Regimen** to modify.

   Note: *If modifying an existing Regimen, select Copy to Personal to keep the original Regimen active.*
3. Complete the **Emetogenic Risk Score**, **Febrile Neutropenic Risk**, and **Version Number**.
4. Add a user-friendly **Name** to make it easy for users to determine which Regimen to use. The **Names** shown in the Regimen builds below are provided as examples.

   Note: *Regimen OPDIVO Qvantig 14-Day Cycles – GC/GEJC/EAC – Combination Therapy and Regimen OPDIVO Qvantig 21-Day Cycles – GC/GEJC/EAC – Combination Therapy should be built for independent utilization per organizational standards.*

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 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

Regimen 14-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig™ 14-Day Cycles – GC/GEJC/EAC – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 600 mg/ 10,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

OR

Regimen 21-Day Cycle:

a. Add **Regimen Name** per organizational naming and numbering standard, for example: **OPDIVO Qvantig 21-Day Cycles – GC/GEJC/EAC – Combination Therapy**
b. Select the appropriate disease(s) from the dropdown and click **Update Calendar**
c. Include appropriate **Cycle & Day** details and click **Save**:
   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**

Note: *Select Copy from Cycle 1 to carry specifics through to additional cycles.*

d. Search for **OPDIVO Qvantig 900 mg/ 15,000 units** by clicking **Add Drug**
e. Select **Edit** to add **Description** 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**
f. Search for **fluoropyrimidine- and platinum-containing chemotherapy** by clicking **Add Drug**
g. Select **Edit** to add **Important Safety Information** details, such as the Package Insert https://packageinserts.bms.com/pi/pi_opdivo-qvantig.pdf
h. Select **Edit** to add any **Warnings** to display each time the **Regimen** is opened
i. Add any additional **Orders** such as:
   i. Patient education
   ii. Supportive care medications
   iii. NCCN parameters
   iv. Appointment requests

5. Once all updates are complete, go back to the top and click **Save** a final time.
6. From the **Select an Action** dropdown, select to **Move (promote) to Practice**.

Consider clicking Save at the top frequently throughout any build/regimen updates.

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment, they can also occur after discontinuation of OPDIVO QVANTIG™ (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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 paresis, autoimmune neuropathy; *ocular:* uveitis, iritis, and other ocular inflammatory toxicities can occur; *gastrointestinal:* pancreatitis to include increases in serum amylase and lipase levels, gastritis, duodenitis; *musculoskeletal and connective tissue:* myositis/polymyositis, rhabdomyolysis, and associated sequelae including renal failure, arthritis, polymyalgia rheumatica; *endocrine:* hypoparathyroidism; *other (hematologic/immune):* hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis (HLH), systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

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

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 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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

Please see additional Important Safety Information for OPDIVO Qvantig on pages 36–41 and U.S. Full Prescribing Information for OPDIVO Qvantig.

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 erythrodysaesthesia syndrome (40%), stomatitis (37%), rash (36%), hypertension (36%), hypothyroidism (34%), musculoskeletal pain (33%), decreased appetite (28%), nausea (27%), dysgeusia (24%), abdominal pain (22%), cough (20%) and upper respiratory tract infection (20%). In Checkmate 025, the most common adverse reactions (≥20%) reported in patients receiving intravenous nivolumab (n=406) vs everolimus (n=397) were fatigue (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 141, the most common adverse reactions (≥10%) in patients receiving intravenous nivolumab (n=236) were cough (14%) and dyspnea (14%) at a higher incidence than investigator's choice. In Checkmate 275, the most common adverse reactions (≥ 20%) reported in patients receiving intravenous nivolumab (n=270) were fatigue (46%), musculoskeletal pain (30%), nausea (22%), and decreased appetite (22%). In Checkmate 274, the most common adverse reactions (20%) reported in patients receiving intravenous nivolumab (n=351) were rash (36%), fatigue (36%), diarrhea (30%), pruritus (30%), musculoskeletal pain (28%), and urinary tract infection (22%). In Checkmate 901, the most common adverse reactions (reported in ≥20% of patients) were nausea (52%), fatigue (48%), musculoskeletal pain (33%), constipation (30%), decreased appetite (30%), rash (25%), vomiting (23%), and peripheral neuropathy (20%). In Checkmate 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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Important Safety Information

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

Surgery Related Adverse Reactions

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

Clinical Trials and Patient Populations

Checkmate 649–previously untreated advanced or metastatic gastric cancer, gastroesophageal junction and esophageal adenocarcinoma; Checkmate 577–adjuvant treatment of esophageal or gastroesophageal junction cancer; Checkmate 238–adjuvant treatment of patients with completely resected Stage III or Stage IV melanoma; Checkmate 76K–adjuvant treatment of patients 12 years of age and older with completely resected Stage IIB or Stage IIC melanoma; Checkmate 274–adjuvant treatment of urothelial carcinoma; Checkmate 275–previously treated advanced or metastatic urothelial carcinoma; 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.

Bristol Myers Squibb®

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