

Patient Monitoring Checklist

Use this chart to help your patient notice and report potential side effects

✍ Before treatment, write down how you are feeling to record a baseline.

- ✍ After treatment begins, use this chart to continue monitoring how you are feeling between oncology clinic visits.
- ✍ If you notice any discomfort or changes in the way you are feeling, contact your Oncology Care Team immediately.

Name of Patient	Name of Doctor or Nurse	Date
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Heart:

- chest pain
- irregular heartbeat or feel like your heart is racing
- shortness of breath
- tiredness
- swelling in your ankles

Hormone Glands:

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Liver:

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Lungs:

- cough
- chest pain
- shortness of breath

Intestines:

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdominal) pain or tenderness

Kidneys:

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

Other Organs:

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO, YERVOY, Opdualag or OPDIVO Qvantig. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

YERVOY (ipilimumab) may be associated with eye problems with signs and symptoms that include blurry vision, double vision, or other vision problems and eye pain or redness.

Skin:

- rash
- itching
- skin blistering or peeling
- swollen lymph nodes
- painful sores or ulcers in the mouth or nose, throat, or genital area
- fever or flu-like symptoms

Severe Infusion Reactions:

- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back or neck pain

If you are taking OPDIVO® (nivolumab) in combination with another medicine, consult your healthcare professional about the potential side effects of that medicine. **Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic) can occur.** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO, OPDIVO + YERVOY® (ipilimumab), YERVOY, Opdualag™ (nivolumab and relatlimab-rmbw), or OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy). Your healthcare provider will monitor you for these complications. These are not all of the possible side effects of OPDIVO, OPDIVO + YERVOY, YERVOY, Opdualag, or OPDIVO Qvantig.

i Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, or OPDIVO Qvantig on pages 2–6, and the U.S. Full Prescribing Information and Medication Guides for [OPDIVO](#), [YERVOY](#), [Opdualag](#), and [OPDIVO Qvantig](#).



Important Safety Information

OPDIVO® (nivolumab), YERVOY® (ipilimumab), OPDUALAG™ (nivolumab and relatlimab-rmbw) and OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) are medicines that may treat certain cancers by working with your immune system. OPDIVO, YERVOY, Opdualag and OPDIVO Qvantig can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO is used in combination with YERVOY or another therapy.

YERVOY can cause serious side effects in many parts of your body which can lead to death. These problems may happen anytime during treatment with YERVOY or after you have completed treatment.

OPDIVO® (nivolumab) and OPDIVO® + YERVOY® (ipilimumab) Indications

OPDIVO® (nivolumab) is a prescription medicine used to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO® (nivolumab) is a prescription medicine used to treat a kind of skin cancer called melanoma. It may be used alone in adults and children 12 years and older with Stage IIB, Stage IIC, Stage III or Stage IV melanoma to help prevent melanoma from coming back after it has been completely removed by surgery.

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early-stage lung cancer (called non-small cell lung cancer).

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early stage lung cancer (called non-small cell lung cancer) that does not have an abnormal EGFR or ALK gene and then may be continued alone after surgery to help prevent your lung cancer from coming back.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of advanced stage lung cancer (called non-small cell lung cancer) when your lung cancer has spread to other parts of your body (metastatic) **and** your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) and 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine, as a first treatment for adults with a type of advanced stage lung cancer (called non-small cell lung cancer) when your lung cancer has spread or comes back, **and** your tumor does not have an abnormal EGFR or ALK gene.

OPDIVO® (nivolumab) is a prescription medicine used to treat adults with a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread **and** you have received chemotherapy that contains platinum, and it did not work or is no longer working. If your tumor has an abnormal EGFR or ALK gene, you should have also received an EGFR or ALK inhibitor medicine and it did not work or is no longer working.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of cancer that affects the lining of the lungs and chest wall called malignant pleural mesothelioma which cannot be removed by surgery.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for certain adults with kidney cancer that has spread (advanced renal cell carcinoma).

OPDIVO® (nivolumab) is a prescription medicine used in combination with cabozantinib as a first treatment for adults with kidney cancer that has spread (advanced renal cell carcinoma). Please read the Patient Information that comes with cabozantinib.

OPDIVO® (nivolumab) is a prescription medicine used to treat people with kidney cancer (renal cell carcinoma) when your cancer has spread after treatment with other cancer medications.

OPDIVO® (nivolumab) is a prescription medicine used to treat people with head and neck cancer (squamous cell carcinoma) that has come back or spread **and** you have received chemotherapy that contains platinum and it did not work or is no longer working.

OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) [urothelial carcinoma] when it has spread (locally advanced or metastatic) and you have received chemotherapy that contains platinum, and it did not work or is no longer working or your cancer worsened within 12 months of treatment with chemotherapy that contains platinum, either before or after surgery to remove your cancer.

OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the lining of the urinary tract (including the bladder, ureters, or renal pelvis) [urothelial carcinoma] to help prevent cancer of the urinary tract from coming back after it was removed by surgery.

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy medicines cisplatin and gemcitabine, as a first line treatment when your urinary tract cancer has spread (metastatic) or cannot be removed by surgery.

OPDIVO® (nivolumab) is a prescription medicine that may be used in combination with YERVOY® (ipilimumab) to treat adults and children 12 years of age and older, with a type of colon or rectal cancer (colorectal cancer) that cannot be removed with surgery, or has spread, and is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

OPDIVO® (nivolumab) is a prescription medicine that may be used alone to treat adults and children 12 years of age and older with a type of colon or rectal cancer (colorectal cancer) that has spread, and is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), and you have received treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of liver cancer called hepatocellular carcinoma that cannot be removed by surgery or has spread.

OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) to treat adults with a type of liver cancer called hepatocellular carcinoma (HCC) when your liver cancer cannot be removed by surgery or has spread, and you have received prior treatment with sorafenib.

OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) if your esophageal cancer is a type called squamous cell carcinoma, and cannot be removed with surgery, **and** has come back or spread after you have received chemotherapy that contains fluoropyrimidine and platinum.

OPDIVO® (nivolumab) is a prescription medicine that may be used in adults to help prevent cancer of the tube that connects your throat to your stomach (esophageal cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer) from coming back after it has been treated with chemoradiation followed by surgery to completely remove the cancer, **but** some cancer cells were still present in the removed tumor or lymph nodes.

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your cancer is a type called squamous cell carcinoma **and** cannot be removed with surgery or has spread, **and** your tumors are positive for PD-L1.



Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig continued on the following page.



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your cancer is a type called squamous cell carcinoma **and** cannot be removed with surgery (advanced) or has spread, **and** your tumors are positive for PD-L1.

OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults with cancer of the stomach (gastric cancer), cancer where the esophagus joins the stomach (gastroesophageal junction cancer), and with esophageal adenocarcinoma when your cancer cannot be removed with surgery or has spread, **and** your tumors are positive for PD-L1.

It is not known if OPDIVO is safe and effective in children younger than 12 years of age with melanoma or MSI-H or dMMR metastatic colorectal cancer.

It is not known if OPDIVO is safe and effective in children for the treatment of any other cancers.

YERVOY® (ipilimumab) Indications

YERVOY® (ipilimumab) is a prescription medicine used in adults and children 12 years of age and older to treat melanoma (a kind of skin cancer) that has spread (metastatic) or cannot be removed by surgery (unresectable), alone or in combination with OPDIVO® (nivolumab).

YERVOY® (ipilimumab) is a prescription medicine used in adults to help prevent melanoma (a kind of skin cancer) from coming back after it and lymph nodes that contain cancer have been removed by surgery.

It is not known if YERVOY is safe and effective in children younger than 12 years of age.

OPDUALAG® (nivolumab and relatlimab-rmbw) Indication

Opdualag™ (nivolumab and relatlimab-rmbw) is a prescription medicine used to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma). It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or older who weigh less than 88 pounds (40 kg), or in children younger than 12 years of age.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) Indications

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone as a first treatment for certain adults with kidney cancer that has spread (advanced renal cell carcinoma), after completing combination treatment with intravenous nivolumab and ipilimumab.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with cabozantinib as a first treatment for adults with kidney cancer that has spread (advanced renal cell carcinoma). Please read the Patient Information that comes with cabozantinib.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used to treat adults with kidney cancer (renal cell carcinoma) when your cancer has spread after treatment with other cancer medications.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma), after completing combination treatment with intravenous nivolumab and ipilimumab.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used to treat a kind of skin cancer called melanoma. It may be used alone in adults with Stage IIB, Stage IIC, Stage III or Stage IV melanoma to help prevent melanoma from coming back after it has been completely removed by surgery.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early-stage lung cancer (called non-small cell lung cancer).

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early stage lung cancer (called non-small cell lung cancer) that does not have an abnormal EGFR or ALK gene and then may be continued alone after surgery to help prevent your lung cancer from coming back.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread and you have received chemotherapy that contains platinum, and it did not work or is no longer working. If your tumor has an abnormal EGFR or ALK gene, you should have also received an FDA-approved therapy for tumors with these abnormal genes, and it did not work or is no longer working.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with head and neck cancer (squamous cell carcinoma) that has come back or spread and you have received chemotherapy that contains platinum and it did not work or is no longer working.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the lining of the urinary tract (including the bladder, ureters, or renal pelvis) [urothelial carcinoma] to help prevent cancer of the urinary tract from coming back after it was removed by surgery.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy medicines cisplatin and gemcitabine, as a first line treatment for adults whose urinary tract cancer has spread (metastatic) or cannot be removed by surgery.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) [urothelial carcinoma] when it has spread (locally advanced or metastatic) and you have received chemotherapy that contains platinum, and it did not work or is no longer working or your cancer worsened within 12 months of treatment with chemotherapy that contains platinum, either before or after surgery to remove your cancer.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone in adults to help prevent cancer of the tube that connects your throat to your stomach (esophageal cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer) from coming back after it has been treated with chemoradiation followed by surgery to completely remove the cancer, but some cancer cells were still present in the removed tumor or lymph nodes.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your cancer is a type called squamous cell carcinoma and cannot be removed with surgery or has spread, **and** your tumors are positive for PD-L1.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) if your esophageal cancer is a type called squamous cell carcinoma, and cannot be removed with surgery, and has come back or spread after you have received chemotherapy that contains fluoropyrimidine and platinum.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults with cancer of the stomach (gastric), junction between the stomach and esophagus (gastroesophageal junction), and esophagus that is a type called esophageal adenocarcinoma and cannot be removed with surgery or has spread, **and** your tumors are positive for PD-L1.

It is not known if OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is safe and effective in children.



Please see Important Safety Information for OPDIVO, YERVOY, Opdualag™, and OPDIVO Qvantig™ continued on the following page.



Important Safety Information for OPDIVO® (nivolumab), YERVOY® (ipilimumab), and OPDIVO +YERVOY

What is the most important information I should know about OPDIVO + YERVOY?

OPDIVO and YERVOY are medicines that may treat certain cancers by working with your immune system. OPDIVO and YERVOY can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **Lung problems:** cough; shortness of breath; chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdominal) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); bleeding or bruising more easily than normal
- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine; blood in your urine; swelling in your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; swollen lymph nodes; painful sores or ulcers in the mouth or nose, throat, or genital area; fever or flu-like symptoms
- **Eye problems:** blurry vision, double vision, or other vision problems; eye pain or redness

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO and YERVOY. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- Chest pain; irregular heartbeat; shortness of breath; swelling of ankles
- Confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs
- Double vision; blurry vision; sensitivity to light; eye pain; changes in eye sight
- Persistent or severe muscle pain or weakness; muscle cramps
- Low red blood cells; bruising

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ transplant that you have had.

Getting medical help right away may help keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. Your healthcare team may also need to delay or completely stop your treatment if you have severe side effects.

Possible side effects of OPDIVO + YERVOY

OPDIVO and OPDIVO + YERVOY can cause serious side effects, including:

- See “What is the most important information I should know about OPDIVO + YERVOY?”
- **Severe infusion reactions.** Tell your healthcare team right away if you get these symptoms during an infusion of OPDIVO or YERVOY: chills or shaking; itching or rash; flushing; shortness of breath or wheezing; dizziness; feel like passing out; fever; back or neck pain

- **Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO or YERVOY. Your healthcare provider will monitor you for these complications.

The most common side effects of OPDIVO, when used alone, include: feeling tired; rash; pain in muscles, bones, and joints; itching; diarrhea; nausea; weakness; cough; shortness of breath; constipation; decreased appetite; back pain; upper respiratory tract infection; fever; headache; stomach-area (abdominal) pain; vomiting; and urinary tract infection.

The most common side effects of OPDIVO, when used in combination with a platinum-containing chemotherapy and chemotherapy, include: nausea; feeling tired; pain in muscles, bones, and joints; constipation; decreased appetite; rash; vomiting; numbness, pain, tingling, or burning in your hands, and feet.

The most common side effects of OPDIVO, when used in combination with YERVOY, include: feeling tired; diarrhea; rash; itching; nausea; pain in muscles, bones, and joints; fever; cough; decreased appetite; vomiting; stomach-area (abdominal) pain; shortness of breath; upper respiratory tract infection; headache; low thyroid hormone levels (hypothyroidism); constipation; decreased weight; and dizziness.

The most common side effects of OPDIVO, when used in combination with YERVOY and a platinum-containing chemotherapy and another chemotherapy, include: feeling tired; pain in muscles, bones, and joints; nausea; diarrhea; rash; decreased appetite; constipation; and itching.

The most common side effects of OPDIVO, when used in combination with cabozantinib, include: diarrhea; feeling tired or weak; liver problems; rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet; mouth sores; rash; high blood pressure; low thyroid hormone levels; pain in muscles, bones, and joints; decreased appetite; nausea; change in the sense of taste; stomach-area (abdominal) pain; cough; upper respiratory tract infection.

The most common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include: nausea; numbness, pain, tingling, or burning in your hands or feet; decreased appetite; feeling tired; constipation; mouth sores; diarrhea; vomiting; stomach-area (abdominal) pain; and pain in muscles, bones, and joints.

The most common side effects of YERVOY include: feeling tired; diarrhea; nausea; itching; rash; vomiting; headache; weight loss; fever; decreased appetite; difficulty falling or staying asleep.

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Before receiving OPDIVO or YERVOY, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant, including corneal transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO and YERVOY can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO or YERVOY passes into your breast milk. Do not breastfeed during treatment with OPDIVO or YERVOY and for 5 months after the last dose of OPDIVO or YERVOY.

Females who are able to become pregnant:

Your healthcare provider should do a pregnancy test before you start receiving OPDIVO or YERVOY.

 Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig continued on the following page.



- You should use an effective method of birth control during your treatment and for 5 months after the last dose of OPDIVO or YERVOY. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO or YERVOY. You or your healthcare provider should contact Bristol-Myers Squibb at 1-844-593-7869 as soon as you become aware of a pregnancy.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Important Safety Information for OPDUALAG (nivolumab and relatlimab-rmbw)

What is the most important information I should know about Opdualag?

Opdualag is a medicine that may treat a type of skin cancer called melanoma by working with your immune system. Opdualag can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

- **Lung problems:** new or worsening cough; shortness of breath; chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdominal) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); bleeding or bruising more easily than normal
- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine; blood in your urine; swelling in your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in the mouth or nose, throat, or genital area
- **Heart Problems:** new or worse chest pain; irregular heartbeat or feel like your heart is racing; shortness of breath; tiredness; swelling in your ankles

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with Opdualag. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- Confusion; sleepiness; memory problems; changes in mood or behavior; stiff neck; balance problems; tingling or numbness of the arms or legs
- Double vision; blurry vision; sensitivity to light; eye pain; changes in eyesight
- Persistent or severe muscle pain or weakness; muscle cramps
- Low red blood cells; bruising

Getting medical help right away may help keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment with Opdualag. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop your treatment with Opdualag if you have severe side effects.

Possible side effects of Opdualag

Opdualag can cause serious side effects, including:

- See “What is the most important information I should know about Opdualag?”

- **Severe infusion reactions.** Tell your healthcare provider or nurse right away if you get these symptoms during an infusion of Opdualag: chills or shaking; itching or rash; flushing; shortness of breath; dizziness; feel like passing out; fever; back or neck pain

- **Complications of stem cell transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Opdualag. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

The most common side effects of Opdualag include: muscle and bone pain; tiredness; decreased red blood cell and white blood cell counts; increased liver function test results; rash; itching, diarrhea; decreased salt (sodium) in your blood.

These are not all the possible side effects of Opdualag. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before receiving Opdualag, tell your healthcare provider if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis, or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. Opdualag can harm your unborn baby

Females who are able to become pregnant:

- your healthcare provider should do a pregnancy test before you start receiving Opdualag
- you should use an effective method of birth control during and for at least 5 months after the last dose of Opdualag. Talk to your healthcare provider about birth control methods that you can use during this time.
- tell your healthcare provider right away if you become pregnant during treatment with Opdualag
- are breastfeeding or plan to breastfeed. It is not known if Opdualag passes into your breast milk. Do not breastfeed during treatment with Opdualag and for 5 months after the last dose of Opdualag.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Important Safety Information for OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy)

What is the most important information I should know about OPDIVO Qvantig?

OPDIVO Qvantig is a medicine that may treat certain cancers by working with your immune system. OPDIVO Qvantig can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time. Some of these problems may happen more often when OPDIVO Qvantig is used in combination with another therapy.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **Lung problems:** cough; shortness of breath; chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky, or have blood or mucus; severe stomach-area (abdominal) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); dark urine (tea colored); bleeding or bruising more easily than normal



Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig on pages 2–6, and the U.S. Full Prescribing Information and Medication Guides for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig.



- **Hormone gland problems:** headaches that will not go away or unusual headaches; eye sensitivity to light; eye problems; rapid heartbeat; increased sweating; extreme tiredness; weight gain or weight loss; feeling more hungry or thirsty than usual; urinating more often than usual; hair loss; feeling cold; constipation; your voice gets deeper; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine; blood in your urine; swelling of your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; swollen lymph nodes, painful sores or ulcers in mouth or nose, throat, or genital area; fever or flu-like symptoms

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO Qvantig. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- Chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ or tissue transplant that you have had.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during treatment with OPDIVO Qvantig. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with OPDIVO Qvantig, if you have severe side effects.

What are the possible side effects of OPDIVO Qvantig?

OPDIVO Qvantig can cause serious side effects, including:

- See “What is the most important information I should know about OPDIVO Qvantig?”
- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO Qvantig. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

The most common side effects of OPDIVO Qvantig when used alone in people with renal cell carcinoma include: pain in muscles, bones, and joints; feeling tired; itchy skin; rash; low thyroid hormone levels; diarrhea; cough; stomach-area (abdominal) pain.

The most common side effects observed with nivolumab given into the vein (intravenous nivolumab), which may be experienced with OPDIVO Qvantig, are shown below.

The most common side effects of intravenous nivolumab when used alone include: feeling tired; rash; pain in muscles, bones, and joints; itchy skin; diarrhea; nausea; weakness; cough; shortness of breath; constipation; decreased appetite; back pain; upper respiratory tract infection; fever; headache; stomach-area (abdominal) pain; vomiting; urinary tract infection.

The most common side effects of intravenous nivolumab when used in combination with cabozantinib as the first treatment for advanced RCC include: diarrhea; feeling tired; liver problems. See “What is the most important information I should know about OPDIVO Qvantig?”; rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet; mouth sores; rash; high blood pressure; low thyroid hormone levels; pain in muscles, bones, and joints; decreased appetite; nausea; change in the sense of taste; stomach-area (abdominal) pain; cough; upper respiratory tract infection.

The most common side effects of intravenous nivolumab when used in combination with platinum-containing chemotherapy and another chemotherapy medicine before having surgery for NSCLC include: nausea; constipation; feeling tired; decreased appetite; rash.

The most common side effects of intravenous nivolumab when used in combination with cisplatin and gemcitabine to treat urothelial cancer include: nausea; feeling tired; pain in muscles, bones, and joints; constipation; decreased appetite; rash; vomiting; numbness, pain, tingling or burning in your hands and feet.

The most common side effects of intravenous nivolumab when used in combination with fluoropyrimidine and platinum-containing chemotherapy to treat esophageal cancer and gastric cancer include: nausea; numbness, pain, tingling, or burning in your hands or feet; decreased appetite; feeling tired; constipation; mouth sores; diarrhea; vomiting; stomach-area (abdominal) pain; pain in muscles, bones, and joints.

These are not all the possible side effects of OPDIVO Qvantig. For more information, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to FDA. Call 1-800-FDA-1088.

Before receiving OPDIVO Qvantig, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant, including corneal transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO Qvantig can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO Qvantig passes into your breast milk. Do not breastfeed during treatment and for 5 months after your last dose of OPDIVO Qvantig.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start receiving OPDIVO Qvantig.
- You should use an effective method of birth control during treatment and for 5 months after your last dose of OPDIVO Qvantig. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO Qvantig.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

 Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig on pages 2–6, and the U.S. Full Prescribing Information and Medication Guides for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig.



Live On-Demand Support Services for You and Your Patients

We're here to help you better understand your medication. These programs are for people who are prescribed OPDIVO® (nivolumab), YERVOY® (ipilimumab), and OPDIVO + YERVOY, Opdualag™ (nivolumab + relatlimab-rmbw), or OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) and their loved ones. Signing up takes less than 5 minutes. Bristol Myers Squibb remains committed to responding to your needs within 24 hours or less.



1-855-OPDIVO-1
(1-855-673-4861)

FOR LIVE SUPPORT AND ASSISTANCE
8:00 AM to 8:00 PM ET, Monday-Friday

Responses provided between
8:00 AM to 8:00 PM ET, Monday-Friday

- Helpful information
- Details about support and advocacy groups

These support resources and more can be found on
www.opdivo.com



Helpful Information

Get useful tips, tools, and educational materials that can help you or your loved one learn more about Opdualag and may help support your care.



Support and Advocacy Groups

We can direct you to organizations that may be helpful for the challenges you may face.



Just call **1-855-OPDUALAG** (1-855-673-8252)
8:00 AM to 8:00 PM ET, Monday-Friday

These support resources and more can be found on
www.Opdualag.com



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