

Patient Monitoring Checklist

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

- Before treatment, write down how your patient is feeling to record a baseline
- After treatment begins, write down any changes that occur

_____ / _____
 Name of Patient Name of Doctor or Nurse Date (baseline entry) (follow-up visit)

Brain: _____
 headache sleepiness
 fever seeing or hearing things that are not really there (hallucinations)
 tiredness or weakness confusion
 memory problems seizures
 stiff neck

Hormone Glands: _____
 (especially the thyroid, pituitary, adrenal glands, and pancreas)
 headaches that will not go away or unusual headaches dizziness or fainting
 extreme tiredness hair loss
 weight gain or weight loss feeling cold
 changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness constipation
 voice gets deeper
 excessive thirst or lots of urine
 low thyroid hormone levels (hypothyroidism)

Liver: _____
 yellowing of your skin or the whites of your eyes dark urine (tea colored)
 severe nausea or vomiting bleeding or bruising more easily than normal
 pain on the right side of your stomach area (abdomen) feeling less hungry than usual
 drowsiness decreased energy

Lungs: _____
 new or worsening cough
 chest pain
 shortness of breath

Intestines: _____
 (colitis that can lead to tears or holes in your intestine)
 diarrhea (loose stools) or more bowel movements than usual
 blood in your stools or dark, tarry, sticky stools
 severe stomach-area (abdomen) pain or tenderness

Kidneys: _____
 (including nephritis and kidney failure)
 decrease in the amount of urine swelling in your ankles
 blood in your urine loss of appetite

Other Organs: _____
 changes in eyesight severe muscle weakness
 severe or persistent muscle or joint pains chest pain

Skin: _____
 rash skin blistering
 itching ulcers in mouth or other mucous membranes

Severe Infusion-Related Reactions:
 chills or shaking difficulty breathing feeling like passing out
 itching or rash dizziness
 flushing fever

Complications of stem cell transplant that uses donor stem cells (allogeneic) have been reported. These complications can be severe and lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant. These are not all of the possible side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab). This is why your patient needs to tell you about any discomfort or changes in the way they are feeling.

INDICATIONS

OPDIVO® (nivolumab) is a prescription medicine used to treat people with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO is a prescription medicine used in combination with YERVOY® (ipilimumab) to treat people with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO is a prescription medicine used to treat people with a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread or grown **and** you have tried 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 tried an FDA-approved therapy for tumors with these abnormal genes, and it did not work or is no longer working.

OPDIVO is a prescription medicine used to treat people with a type of advanced stage lung cancer (called small cell lung cancer) that has spread or grown and you have tried at least two different types of chemotherapy, including one that contains platinum, and it did not work or is no longer working. OPDIVO was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

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

OPDIVO is a prescription medicine used in combination with YERVOY to treat kidney cancer (renal cell carcinoma) in certain people when their cancer has spread.

OPDIVO is a prescription medicine used to treat adults with a type of blood cancer called classical Hodgkin lymphoma if your cancer has come back or spread after a type of stem cell transplant that uses your own stem cells (autologous), **and** you used the drug brentuximab vedotin before or after your stem cell transplant, **or** if you received at least 3 kinds of treatment including an autologous stem cell transplant. OPDIVO was approved based on response rate. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

OPDIVO 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 tried chemotherapy that contains platinum and it did not work or is no longer working.

OPDIVO is a prescription medicine used to treat people with bladder cancer (urothelial carcinoma) that has spread or grown and you have tried chemotherapy that contains platinum, and it did not work or is no longer working. OPDIVO was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

OPDIVO is a prescription medicine used to treat adults and children 12 years of age and older with a type of colon or rectal cancer (colorectal cancer) that has spread to other parts of the body (metastatic), is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), **and** you have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working. OPDIVO was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

OPDIVO is a prescription medicine 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 has spread to other parts of the body (metastatic), is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), **and** you have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working. OPDIVO in combination with YERVOY was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO in combination with YERVOY for this use.

OPDIVO is a prescription medicine used to treat people with liver cancer (hepatocellular carcinoma) if you have previously received treatment with sorafenib. OPDIVO was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

OPDIVO is a prescription medicine used in combination with YERVOY to treat people with liver cancer (hepatocellular carcinoma) if you have previously received treatment with sorafenib. OPDIVO in combination with YERVOY was approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO in combination with YERVOY for this use.

OPDIVO is a prescription medicine used to treat people with a type of skin cancer called melanoma to help prevent melanoma from coming back after it and lymph nodes that contain cancer have been removed by surgery.

It is not known if OPDIVO is safe and effective in children younger than 12 years of age with MSI-H or dMMR metastatic colorectal cancer, **or** in children younger than 18 years of age for the treatment of any other cancers

Important Safety Information for OPDIVO and OPDIVO + YERVOY

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO 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 serious or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when OPDIVO is used in combination with YERVOY.

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.

Serious side effects may include:

- **Lung problems (pneumonitis).** Symptoms of pneumonitis may include: new or worsening cough; chest pain; and shortness of breath.
- **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include: diarrhea (loose stools) or more bowel movements than usual; blood in your stools or dark, tarry, sticky stools; and severe stomach area (abdomen) pain or tenderness.
- **Liver problems (hepatitis).** Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach area (abdomen); drowsiness; dark urine (tea colored); bleeding or bruising more easily than normal; feeling less hungry than usual; and decreased energy.

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Important Safety Information for OPDIVO and the OPDIVO + YERVOY Regimen (cont'd)

Serious side effects (cont'd)

- **Hormone gland problems (especially the thyroid, pituitary, adrenal glands, and pancreas).** Signs and symptoms that your hormone glands are not working properly may include: headaches that will not go away or unusual headaches; extreme tiredness; weight gain or weight loss; dizziness or fainting; changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness; hair loss; feeling cold; constipation; voice gets deeper; and excessive thirst or lots of urine.
- **Kidney problems, including nephritis and kidney failure.** Signs of kidney problems may include: decrease in the amount of urine; blood in your urine; swelling in your ankles; and loss of appetite.
- **Skin problems.** Signs of these problems may include: rash; itching; skin blistering; and ulcers in the mouth or other mucous membranes.
- **Inflammation of the brain (encephalitis).** Signs and symptoms of encephalitis may include: headache; fever; tiredness or weakness; confusion; memory problems; sleepiness; seeing or hearing things that are not really there (hallucinations); seizures; and stiff neck.
- **Problems in other organs.** Signs of these problems may include: changes in eyesight; severe or persistent muscle or joint pains; severe muscle weakness; and chest pain.

Additional serious side effects observed during a separate study of YERVOY alone include:

- **Nerve problems that can lead to paralysis.** Symptoms of nerve problems may include: unusual weakness of legs, arms, or face; and numbness or tingling in hands or feet.
- **Eye problems.** Symptoms may include: blurry vision, double vision, or other vision problems; and eye pain or redness.

Get medical help immediately if you develop any of these symptoms or they get worse. It may keep these problems from becoming more serious. Your healthcare team will check you for side effects during treatment and may treat you with corticosteroid or hormone replacement medicines. If you have a serious side effect, your healthcare team may also need to delay or completely stop your treatment.

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

- **Severe infusion-related reactions.** Tell your doctor or nurse right away if you get these symptoms during an infusion of OPDIVO: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; and feeling like passing out.
- **Complications of stem cell transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

Pregnancy and Nursing:

- Tell your healthcare provider if you are pregnant or plan to become pregnant. OPDIVO and YERVOY can harm your unborn baby. If you are a female who is able to become pregnant, your healthcare provider should do a pregnancy test before you start receiving OPDIVO. Females who are able to become pregnant should use an effective method of birth control during and for at least 5 months after the last dose. 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 are pregnant during treatment. You or your healthcare provider should contact Bristol Myers Squibb at 1-800-721-5072 as soon as you become aware of the pregnancy.

- **Pregnancy Safety Surveillance Study:** Females who become pregnant during treatment with YERVOY are encouraged to enroll in a Pregnancy Safety Surveillance Study. The purpose of this study is to collect information about the health of you and your baby. You or your healthcare provider can enroll in the Pregnancy Safety Surveillance Study by calling 1-844-593-7869.
- Before receiving treatment, tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if either treatment passes into your breast milk. Do not breastfeed during treatment and for 5 months after the last dose.

Tell your healthcare provider about:

- Your health problems or concerns if you: have immune system problems such as autoimmune disease, Crohn's disease, ulcerative colitis, lupus, or sarcoidosis; have had an organ transplant; have lung or breathing problems; have liver problems; or have any other medical conditions.
- All the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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

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; abdominal pain; shortness of breath; upper respiratory tract infection; headache; low thyroid hormone levels (hypothyroidism); decreased weight; and dizziness. The most common side effects of YERVOY include: feeling tired; diarrhea; nausea; itching; rash; vomiting; headache; weight loss; fever; decreased appetite; and difficulty falling or staying asleep.

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see U.S. Full Prescribing Information and Medication Guide for OPDIVO and YERVOY, including **Boxed WARNING regarding immune-mediated side effects** for YERVOY at OPDIVO.com.



Please see Important Safety Information for OPDIVO and YERVOY, including Boxed WARNING regarding immune-mediated adverse reactions for YERVOY on pages 2-3, and U.S. Full Prescribing Information for OPDIVO and YERVOY.



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