

Patient Pocket Guide

A guide to identify signs and symptoms of potential side effects while on immunotherapy, including immune-mediated side effects

- 1 Detach the wallet card and keep on your person at all times**
 - Fill out the treating oncologist's contact information
- 2 Read the information inside and use the Signs and Symptoms Checklist to recognize what to report immediately**
 - Call your treating oncologist right away if you experience anything unusual while on OPDIVO or OPDIVO + YERVOY therapy
 - Contact your oncologist immediately if you experience any symptoms listed on this Signs and Symptoms Checklist, or they get worse. **Getting medical treatment right away may keep the problem from becoming more serious**
- 3 Show this wallet card during any urgent care/emergency room visit**
 - Tell the urgent care/emergency room staff that you are being treated with OPDIVO or OPDIVO + YERVOY and show them the “doctor/nurse” section of this wallet card

Please call my oncologist.
I have received an immunotherapy called:

Drug(s) Name:

Patient Name:

Oncologist Name:

Oncologist Phone Number:

Present this card **every time** you see a doctor or nurse.

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Please see *Important Safety Information* for OPDIVO and YERVOY, including **Boxed WARNING for YERVOY regarding immune-mediated side effects**, on pages 4-6 and the U.S. Full Prescribing Information and Medication Guide for OPDIVO and YERVOY.



Keep this guide handy for your reference. This guide includes a helpful checklist of Signs and Symptoms for you to closely monitor. Call your Oncology Care Team if you have any of these signs or symptoms, or if they get worse.

These are not all of the possible side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab). This is why you need to report any discomfort or changes in the way you are feeling to your Oncology Care Team.

Do not treat symptoms yourself

Symptoms may occur anytime during treatment or even after your treatment has ended

Do not feel embarrassed or that you are bothering your oncologist



Brain

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



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)
- drowsiness
- dark urine (tea colored)
- bleeding or bruise more easily than normal
- feeling less hungry than usual
- decreased energy



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

Other Organs

- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness
- chest pain

Severe Infusion Reactions

- chills or shaking
- itching or rash
- flushing
- difficulty breathing
- dizziness
- fever
- feeling like passing out



Hormone Glands

(especially the thyroid, pituitary, adrenal glands, and pancreas)

- headaches that will not go away or unusual headaches
- extreme tiredness
- weight gain or weight loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- dizziness or fainting
- hair loss
- feeling cold
- constipation
- voice gets deeper
- excessive thirst or lots of urine



Lungs

- new or worsening cough
- chest pain
- shortness of breath



Kidneys

(including nephritis and kidney failure)

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



Skin

- rash
- itching
- skin blistering
- ulcers in mouth or other mucous membranes

Complications of stem cell transplant that uses donor stem cells (allogeneic). 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.

Additional serious side effects of YERVOY alone include: nerve problems that can lead to paralysis; and eye problems.

Please see Important Safety Information for OPDIVO and YERVOY, including **Boxed WARNING for YERVOY regarding immune-mediated side effects**, on the following page and the U.S. Full Prescribing Information and Medication Guide for OPDIVO and YERVOY.

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

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.
- **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.

Continued on next page

Please see Important Safety Information for OPDIVO and YERVOY, including **Boxed WARNING for YERVOY regarding immune-mediated side effects for YERVOY**, on the following page and the U.S. Full Prescribing Information and Medication Guide for [OPDIVO](#) and [YERVOY](#).

Important Safety Information for OPDIVO® (nivolumab) and YERVOY® (ipilimumab) (cont'd)

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.

Getting medical treatment right away may keep these problems from becoming more serious.

Your healthcare provider will check you for these problems during treatment. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment, if you have severe side effects.

OPDIVO can cause serious side effects, including:

- **Severe infusion 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. 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 of OPDIVO. 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 3 months after the last dose of YERVOY.

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; 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; rash; diarrhea; nausea; fever; pain in muscle, bones, and joints; itching; abdominal pain; vomiting; cough; decreased appetite; and shortness of breath. 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.

YERVOY (5mg/mL) is an injection for intravenous (IV) use.

*Please see U.S. Full Prescribing Information and Medication Guide for [OPDIVO](#) and [YERVOY](#), including **Boxed WARNING** regarding immune-mediated side effects for YERVOY.*



Flip Open for Information to Monitor Your Signs and Symptoms

OPDIVO® (nivolumab) 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).
- 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.
- kidney cancer (renal cell carcinoma) in certain people when their cancer has spread.

OPDIVO 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).
- 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.
- 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.
- kidney cancer (renal cell carcinoma) when your cancer has spread or grown after treatment with other cancer medications.
- 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 (Adcetris®) 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.
- 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.

- 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.
- 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.
- people with liver cancer (hepatocellular carcinoma) after you have received treatment with Nexavar® (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.
- 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.

SELECT IMPORTANT SAFETY INFORMATION

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.

*Please see Important Safety Information for OPDIVO and YERVOY, including **Boxed WARNING for YERVOY regarding immune-mediated side effects**, on the following page and the U.S. Full Prescribing Information and Medication Guide for OPDIVO and YERVOY.*

Live On-Demand Support Services for You and Your Patients



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

Bristol-Myers Squibb remains committed to responding to your needs within 24 hours or less



OPDIVO® (nivolumab) Patient Support Offering a range of services

- Patient support
- Downloadable educational materials for your patients
- Contact the Care Navigator



Customer Relations

- Available to answer your general questions concerning Bristol-Myers Squibb products and services

You can also request a visit from an Immuno-Oncology Clinical Liaison for an in-office review of managing immune-mediated adverse reactions

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YERVOY (5 mg/mL) is an injection for intravenous (IV) use.



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Use this checklist to help monitor how you are feeling between oncology clinic visits. Your Oncology Care Team needs to know if you experience any changes in how you are feeling.



Do you have any signs or symptoms?



1. If you notice any discomfort or changes in the way you are feeling, contact your Oncology Care Team immediately.
 2. Getting medical treatment right away may stop these problems from becoming more serious. Do not try to treat possible side effects yourself.
 3. Your oncologist may decide to delay or completely stop OPDIVO® (nivolumab) or YERVOY® (ipilimumab) or give you other medicines to treat your symptoms.
- ▶ **These are not all of the possible side effects of OPDIVO and OPDIVO + YERVOY. This is why you need to report any discomfort or changes in the way you are feeling to your Oncology Care Team. Signs or changes to look out for include...**



Brain

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



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)
- drowsiness
- dark urine (tea colored)
- bleeding or bruise more easily than normal
- feeling less hungry than usual
- 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



Hormone Glands

(especially the thyroid, pituitary, adrenal glands, and pancreas)

- headaches that will not go away or unusual headaches
- extreme tiredness
- weight gain or weight loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- dizziness or fainting
- hair loss
- feeling cold
- constipation
- voice gets deeper
- excessive thirst or lots of urine



Kidneys

(including nephritis and kidney failure)

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



Skin

- rash
- itching
- skin blistering
- ulcers in mouth or other mucous membranes

Other Organs

- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness
- chest pain

Severe Infusion Reactions

- chills or shaking
- itching or rash
- flushing
- difficulty breathing
- dizziness
- fever
- feeling like passing out

Additional serious side effects of YERVOY alone include: nerve problems that can lead to paralysis; and eye problems.



If you experience a severe side effect, you may need to go to a *hospital emergency department*. If this happens, you need to:

- Bring the wallet card and a full list of your medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- Tell doctors and nurses in the emergency department that **you are on an immunotherapy treatment** to treat your condition
- Make sure your Oncology Care Team is notified

Please see *Important Safety Information for OPDIVO and YERVOY, including **Boxed WARNING for YERVOY regarding immune-mediated side effects**, on pages 4-6 and the U.S. Full Prescribing Information and Medication Guide for [OPDIVO](#) and [YERVOY](#).*



Please call my oncologist.

I have received an immunotherapy called:

Drug(s) Name:

Patient Name:

Oncologist Name:

Oncologist Phone Number:

Present this card **every time** you see a doctor or nurse.

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IMPORTANT Information for Doctors/Nurses



ATTENTION

Call patient's doctor
prior to prescribing
other medications

Do not wait to treat the patient if urgent care is required.



For more information, visit <http://www.opdivohcp.com/patientmanagementresources>
or call **1-855-OPDIVO-1 (1-855-673-4861)**