For people 12 years of age and older whose MSI-H/dMMR CRC has spread to other parts of the body (metastatic) and who have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

1ST + ONLY COMBINATION OF 2 IMMUNOTHERAPIES

What is OPDIVO?

OPDIVO is a prescription medicine used to treat adults and children 12 years of age or older who have colorectal cancer (a type of colon or rectal cancer), and who:

- Have colorectal cancer that has spread to other parts of the body (metastatic); AND
- Have a tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); AND
- Have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

OPDIVO can be used alone or in combination with YERVOY (OPDIVO + YERVOY). OPDIVO and OPDIVO + YERVOY were approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO and OPDIVO + YERVOY for this use.

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.

*OPDIVO (10 mg/mL) and YERVOY (5 mg/mL) are injections for intravenous (IV) use.*

Information provided in this brochure is not a substitute for talking with your healthcare professional. Your healthcare professional is the best source of information about your disease.

Please see additional Important Facts for OPDIVO and YERVOY.
OPDIVO® (nivolumab) + YERVOY® (ipilimumab)
May Give Appropriate Patients Another Chance to Fight

About the OPDIVO + YERVOY Clinical Trial

OPDIVO + YERVOY was studied in a clinical trial of 119 people whose MSI-H/dMMR CRC had spread to other parts of the body (metastatic) and who were treated with at least one prior line of therapy that would have included fluoropyrimidine-, oxaliplatin-, or irinotecan-based chemotherapy.

Of the 119 people included in the clinical trial, 82 received prior treatment with all three of the following: fluoropyrimidine, oxaliplatin, and irinotecan.

Clinical Trial Results

After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

56% (46 of 82 people) had their tumors shrink or disappear completely
43% (35 of 82) saw their tumors shrink (partial response)
13% (11 of 82) saw their tumors disappear completely (complete response)

This clinical trial is still ongoing

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune-related adverse events. For more information, see Important Facts.
Of the 119 people included in the clinical trial, 82 received prior treatment with all three of the following: fluoropyrimidine, oxaliplatin, and irinotecan.

Clinical Trial Results
After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

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43% (35 of 82) saw their tumors shrink (partial response)
13% (11 of 82) saw their tumors disappear completely (complete response)

This clinical trial is still ongoing

The study was designed to look at overall response rate (ORR). ORR is the percentage of people who responded to treatment. These people saw their tumors either shrink (partial response) or disappear completely (complete response).

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

Ask your doctor if this treatment option is right for you. OPDIVO + YERVOY will not work for everyone. Individual results may vary.
Of the 119 people included in the clinical trial, 82 received prior treatment with all three of the following: fluoropyrimidin, oxaliplatin, and irinotecan.

**Clinical Trial Results**

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Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

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Opdivo + Yervoy

Of the 119 people included in the clinical trial, 82 received prior treatment with all three of the following: fluoropyrimidine, oxaliplatin, and irinotecan.

Clinical Trial Results

After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

- 56% (46 of 82 people) had their tumors shrink or disappear completely
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This clinical trial is still ongoing

The study was designed to look at overall response rate (ORR). ORR is the percentage of people who responded to treatment. These people saw their tumors either shrink (partial response) or disappear completely (complete response).

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for Opdivo and Yervoy in links below.

Ask your doctor if this treatment option is right for you. Opdivo + Yervoy will not work for everyone. Individual results may vary.

You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.
**OPDIVO**® (nivolumab) May Give Appropriate Patients Another Chance to Fight

**About the OPDIVO Clinical Trial**

OPDIVO was studied in a clinical trial of 74 people whose MSI-H/dMMR CRC had spread to other parts of the body (metastatic) and who were treated with at least one prior line of therapy that would have included fluoropyrimidine-, oxaliplatin-, or irinotecan-based chemotherapy.

Of the 74 people included in the clinical trial, 53 received prior treatment with all three of the following: fluoropyrimidine, oxaliplatin, and irinotecan.

**Clinical Trial Results**

After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

- **32%** (17 of 53 people) had their tumors shrink or disappear completely
- **23%** (12 of 53) saw their tumors shrink (partial response)
- **9%** (5 of 53) saw their tumors disappear completely (complete response)

This clinical trial is still ongoing.

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**SELECT IMPORTANT SAFETY INFORMATION**

**What are the serious side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)?**

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

**Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune-related problems.**
Of the 74 people included in the clinical trial, 53 received prior treatment with all three of the following: fluoropyrimidine, oxaliplatin, and irinotecan.

Clinical Trial Results

After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

- **32%** (17 of 53 people) had their tumors shrink or disappear completely
- **23%** (12 of 53) saw their tumors shrink (partial response)
- **9%** (5 of 53) saw their tumors disappear completely (complete response)

This clinical trial is still ongoing

The study was designed to look at overall response rate (ORR) and duration of response (DoR). ORR is the percentage of people who responded to treatment. These people saw their tumors either shrink (partial response) or disappear completely (complete response). The duration of response is the measure of how long the response lasts.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

Ask your doctor if this treatment option is right for you. OPDIVO + YERVOY will not work for everyone. Individual results may vary.
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After treatment with a fluoropyrimidine, oxaliplatin, and irinotecan:

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The study was designed to look at overall response rate (ORR) and duration of response (DoR). ORR is the percentage of people who responded to treatment. These people saw their tumors either shrink (partial response) or disappear completely (complete response). The duration of response is the measure of how long the response lasts.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

Ask your doctor if this treatment option is right for you. OPDIVO + YERVOY will not work for everyone. Individual results may vary.
OPDIVO + YERVOY

OPDIVO + YERVOY
OPDIVO
YERVOY

Your immune system activates T cells to protect you from foreign threats, including cancer. But cancer cells can hide from T cells and make them inactive.

OPDIVO + YERVOY join forces in different but complementary ways to help your active T cells.

With OPDIVO + YERVOY, more active T cells may be able to help seek and destroy cancer cells.

Some active T cells generated with YERVOY can become memory T cells, which may help recognize and defend against these threats in the future.

The clinical significance of memory T cells (how well their response could treat cancer) is not yet known or understood.

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems. Other problems may also occur.

Prescribing Information:  
Medication Guide:  
OPDIVO  
YERVOY
OPDIVO and YERVOY can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after 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. Your doctor will check you for these problems during treatment. Your doctor 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.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
OPDIVO and YERVYO can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after 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 YERVYO. Your doctor will check you for these problems during treatment. Your doctor 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.

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OPDIVO and YERVOY can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after 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. Your doctor will check you for these problems during treatment. Your doctor 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.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
Help Seek and Attack:
How OPDIVO works with your immune system

Your immune system activates T cells to protect you from foreign threats, including cancer. But cancer cells can hide from T cells and make them inactive.

OPDIVO + YERVOY

OPDIVO Helps active T cells identify cancer cells that are hiding.

With OPDIVO, more active T cells may be able to help seek and attack cancer cells.

ACTIVE T CELLS

OPDIVO can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment. Your doctor 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 your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment. Your doctor 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.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
How OPDIVO works with your immune system

Your immune system activates T cells to protect you from foreign threats, including cancer. But cancer cells can hide from T cells and make them inactive.

OPDIVO can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment. Your doctor 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.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVYO in links below.

The most common side effects of OPDIVO when used in combination with YERVY 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
OPDIVO can cause your T cells to attack healthy cells contained within 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, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment. Your doctor 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.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
Getting an OPDIVO® (nivolumab) + YERVOY® (ipilimumab) Infusion

These are general recommendations about treatment timing and dosing based on a clinical trial. Only your doctor can make specific recommendations about your treatment with OPDIVO + YERVOY.

Here’s a quick look at the 2-phase treatment schedule for patients weighing 88 lbs. or more—including flexible options for the second phase.*

Phase 1 • Start with OPDIVO + YERVOY

- Start
- Week 3
- Week 6
- Week 9

After Week 9

You’ll have 3 weeks before Phase 2

Dosing will be determined by your doctor based upon weight

Infusion times:
- 30 minutes OPDIVO
- 30 minutes YERVOY

Phase 2 • Continue with just OPDIVO

- 340 mg
- 480 mg

Your doctor can help answer questions about any differences between dosing options

Continue treatment every 2 or 4 weeks as long as it is working and side effects are tolerable

OPDIVO and YERVOY are 2 different medicines that are delivered into your vein through an intravenous (IV) line. In the first phase of treatment, you will be given separate infusions of OPDIVO and then YERVOY during the same visit.

Talk to your doctor to learn how many treatments may be right for you. These are the recommendations about

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:
- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune

Prescribing Information: OPDIVO YERVOY
Medication Guide: OPDIVO YERVOY
OPDIVO and YERVOY are 2 different medicines that are delivered into your vein through an intravenous (IV) line. In the first phase of treatment, you will be given separate infusions of OPDIVO and then YERVOY during the same visit.

**Talk to your doctor to learn how many treatments may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointment to let them know how you’re feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

See Important Facts for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.

**If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week to make them easier to remember. It is important to keep all appointments with your healthcare team. If you miss one, call your healthcare team as soon as possible to reschedule your appointment.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.
OPDIVO and YERVOY are two different medicines that are delivered into your vein through an intravenous (IV) line. In the first phase of treatment, you will be given separate infusions of OPDIVO and then YERVOY during the same visit.

Talk to your doctor to learn how many treatments may be right for you. These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

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**OPDIVO** and **YERVOY** are different medicines that are delivered into your vein through an intravenous (IV) line. In the first phase of treatment, you will be given separate infusions of OPDIVO and then YERVOY during the same visit.

**Talk to your doctor to learn how many treatments may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointment to let them know how you’re feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

See **Important Facts** for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.

**If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week to make them easier to remember. It is important to keep all appointments with your healthcare team. If you miss one, call your healthcare team as soon as possible to reschedule your appointment.

Please see **Important Facts** about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

**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)
- decreased weight
- dizziness

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Please see additional **Important Facts** for OPDIVO and YERVOY.
Getting an OPDIVO® (nivolumab) Infusion

These are general recommendations about treatment timing and dosing based on a clinical trial. Only your doctor can make specific recommendations about your treatment with OPDIVO.

Talk to your doctor about which option is right for you.

OPDIVO 240 mg

OPDIVO 480 mg

every 2 weeks
An option that has regularly scheduled time with your healthcare team

every 4 weeks
Offers more time between appointments

1st scan at about week 6
Continue treatment every 2 or 4 weeks as long as it is working and side effects are tolerable

Infusion time 30 minutes

*Your doctor can help answer questions about any differences between dosing options.

OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.

Talk to your doctor to learn how many treatments may be right for you. These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will check your progress regularly.

OPDIVO + YERVOY

OPDIVO

SELECT IMPORTANT SAFETY INFORMATION

What are the serious side effects of OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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.

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

- Lung problems
- Intestinal problems
- Liver problems
- Hormone gland problems
- Kidney problems
- Skin problems
- Eye problems

Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems.
OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.

**Talk to your doctor to learn how many treatments may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointment to let them know how you’re feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

**See Important Facts for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.**

**If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week to make them easier to remember. It is important to keep all appointments with your healthcare team. If you miss one, call your healthcare team as soon as possible to reschedule your appointment.

**Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.**

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**IMPORTANT FACTS**

+ Severe infusion reactions
+ Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).

**What are the most common side effects of OPDIVO and OPDIVO + YERVOY?**

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
OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.

Talk to your doctor to learn how many treatments may be right for you. These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointment to let them know how you're feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

See Important Facts for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.

If you miss an appointment, call a healthcare provider right away. Try to schedule your appointments for the same day of the week to make them easier to remember. It is important to keep all appointments with your healthcare team. If you miss one, call your healthcare team as soon as possible to reschedule your appointment.

Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVVOY in links below.
OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.

**Talk to your doctor to learn how many treatments may be right for you.** These are the recommendations about treatment, timing, and dosing. Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointment to let them know how you’re feeling and ask any questions you may have. You may also be able to talk with others going through a similar situation.

**See Important Facts** for information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment.

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Please see Important Facts about side effects on the right panel. Please see full Prescribing Information and Medication Guides for OPDIVO and YERVOY in links below.

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)
- decreased weight
- dizziness

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Please see additional Important Facts for OPDIVO and YERVOY.
Important Facts About OPDIVO® (nivolumab) and OPDIVO + YERVOY® (ipilimumab)

This is a summary of important information that you need to know about OPDIVO and OPDIVO + YERVOY. Your healthcare team can work with you to help answer any questions you may have about these medications. Keep this information in a safe place so you can refer to it before and during your treatment.

What is OPDIVO?

OPDIVO is a prescription medicine used to treat adults and children 12 years of age or older who have colorectal cancer (a type of colon or rectal cancer), and who:

- Have colorectal cancer that has spread to other parts of the body (metastatic): AND
- Have a tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR): AND
- Have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

OPDIVO can be used alone or in combination with YERVOY (OPDIVO + YERVOY). OPDIVO and OPDIVO + YERVOY were approved based on response rate and how long patients' responses lasted. There is ongoing evaluation of clinical benefit of OPDIVO and OPDIVO + YERVOY for this use.

*OPDIVO (10 mg/mL) and YERVOY (5 mg/mL) are injections for intravenous (IV) use.*

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.

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. Some of these problems may happen more often when OPDIVO is used in combination with another therapy.

Get medical help immediately if you develop any of these signs or symptoms or they get worse. It may keep these problems from becoming more severe.

Prescribing Information: OPDIVO  YERVOY  Medication Guide: OPDIVO  YERVOY
Get medical help immediately if you develop any of these signs or symptoms or they get worse. It may 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. If you have severe side effects, your healthcare team may also need to delay or completely stop your treatment.

What are the serious side effects of OPDIVO and OPDIVO + YERVOY?

A serious side effect is a side effect that can sometimes become severe or life-threatening and can lead to death. They 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** — Things to look out for may include:
- new or worsening cough
- shortness of breath
- chest pain

**Intestinal problems** — Things to look out for may include:
- 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** — Things to look out for may include:
- yellowing of your skin or the whites of your eyes
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

**Hormone gland problems** — Things to look out for may include:
- 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 — Things to look out for may include:
- decrease in your amount of urine
- blood in your urine

Skin problems — Things to look out for may include:
- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in the mouth or nose, throat, or genital area

Eye problems — Things to look out for may include:
- 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 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 eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

What are the possible side effects of OPDIVO + YERVOY?

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

See the previous section, “What is the most important information I should know about OPDIVO + YERVOY?”

Severe infusion reactions — Things to look out for may include:
**Severe infusion reactions** — Things to look out for may include:

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

*Talk to your healthcare team* right away if you get these symptoms during an infusion of OPDIVO or YERVOY.

Complications, including graft-versus-host disease (GVHD), of 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 or YERVOY. Your healthcare provider will monitor you for these complications.

### What are the most common side effects?

The most common side effects of OPDIVO with 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
- stomach-area (abdominal) pain

The most common side effects of OPDIVO when used in combination with YERVOY include:

- feeling tired
- diarrhea
- rash
- fever
- cough
- decreased appetite
- upper respiratory tract infection
- headache
- low thyroid hormone levels (hypothyroidism)
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)
- decreased weight
- dizziness

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

What should I discuss with my healthcare team before receiving OPDIVO or YERVOY?

Tell your healthcare provider about all your medical conditions, including 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 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.
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Females who are able to become pregnant:
Your healthcare provider should do a pregnancy test before you start receiving OPDIVO or YERVOY.

- You should use an effective method of birth control during your treatment and for at least 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 medicines
- over-the-counter medicines
- vitamins
- herbal supplements

For more information, please see U.S. Full Prescribing Information and Medication Guide for OPDIVO. Please see U.S. Full Prescribing Information and Medication Guide for YERVOY, or talk to your healthcare team.
SIGN UP for OPDIVO with You.

*OPDIVO with You* means just that: we’re here to help you better understand OPDIVO, whether you or a loved one are just considering OPDIVO or already have an OPDIVO prescription. This complimentary program includes the following resources. Sign up and you’ll receive:

**Helpful Information**
Get useful tips, tools, and educational materials that can help you learn more about OPDIVO 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.

**A Care Counselor as Close as Your Phone**
If you are prescribed OPDIVO and sign up for this additional resource, you’ll be able to speak with a registered nurse. This personal Care Counselor can answer questions about treatment and help you to be a more informed partner with your doctor. Care Counselors cannot provide medical advice. Your healthcare professional is the best source of information about your health.

If you’d like to sign up for the OPDIVO with You program, or if you have general questions about OPDIVO, call 1-855-OPDIVO-1 (1-855-673-4861) 8 AM to 8 PM ET, Monday to Friday, or visit [www.OPDIVOwithYou.com](http://www.OPDIVOwithYou.com)

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Bristol Myers Squibb is committed to helping patients throughout their treatment

Please see [Important Facts](#) for OPDIVO and YERVOY. Please see links below for full Prescribing Information and Medication Guides for OPDIVO and YERVOY.
Financial Resources

Patient Access, Reimbursement, and Co-Pay Support

Available through Bristol Myers Squibb Access Support®

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That’s why we offer the BMS Access Support program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

For more information, ask your doctor, visit BMS Access Support, or call BMS Access Support at 1-800-861-0048, 8 AM to 8 PM ET, Monday-Friday.

Other Patient Resources*

Fight Colorectal Cancer
www.fightcolorectalcancer.org

We FIGHT to cure colorectal cancer and serve as relentless champions of hope for all affected by this disease through informed patient support, impactful policy change, and breakthrough research endeavors.

Colorectal Cancer Alliance
www.ccalliance.org

The mission of the Colorectal Cancer Alliance is to empower a nation of allies who work with us to provide support for patients and families, caregivers, and survivors; to raise awareness of preventive measures; and to fund critical, life-saving research.

Colon Cancer Coalition
www.coloncancercoalition.org

The Colon Cancer Coalition is dedicated to encouraging screening and supporting patients faced with colon and rectal cancer. By making the words colon, colorectal, and colonoscopy a part of the everyday language, we believe we can overcome the fear and decrease deaths from this largely preventable cancer.

The Raymond Foundation
www.theraymondfoundation.org

The Raymond Foundation is passionate and relentless in our efforts to eradicate gastrointestinal cancers. We champion early detection and overall gastrointestinal (GI) wellness by meaningful outreach and education. By empowering those living with or at risk for GI cancers, we are confident that a cure is in sight.
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Other Patient Resources*

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Michael’s Mission
www.michaelsmission.org

Michael’s Mission is focused on improving the quality of life and treatment options for those affected by colorectal cancer through education, research, and patient support.

CancerCare
www.cancercare.org

The mission of CancerCare is to provide free professional support services to anyone affected by cancer.

Cancer Research Institute
www.cancerresearch.org

Cancer Research Institute (CRI) is dedicated to pursuing research in and advancing awareness of immunotherapy for cancer.

Cancer Support Community
www.cancersupportcommunity.org

This group is an international nonprofit dedicated to providing support, education, and hope to people affected by cancer and their loved ones.

*Bristol Myers Squibb does not endorse these organizations. The information and links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician’s medical advice.
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Please see Important Facts for OPDIVO and YERVOY. Please see links below for full Prescribing Information and Medication Guides for OPDIVO and YERVOY.

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7356US2003558-01-01  02/21