Your Guide to Treatment with YERVOY® (ipilimumab)

Indication:
YERVOY (ipilimumab) is a prescription medicine used in adults to treat melanoma (a kind of skin cancer) that has spread or cannot be removed by surgery.

It is not known if YERVOY is safe and effective in children less than 18 years of age.

Models used for illustrative purposes only.

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. This brochure is intended for U.S. residents 18 years of age or older.

Please see Important Safety Information, including Boxed WARNING regarding immune-mediated side effects, on pages 14-15.

Bristol-Myers Squibb
YERVOY (ipilimumab)

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**Select Important Safety Information**

YERVOY can cause serious side effects in many parts of your body which can lead to death. These serious side effects may include: inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis; inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work; and inflammation of the eyes.

These side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with YERVOY. Your oncologist may decide to delay or stop YERVOY.

Call your healthcare provider if you have any signs or symptoms or they get worse. Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed. Do not try to treat symptoms yourself.

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YOUR DOCTOR HAS PRESCRIBED YERVOY (ipilimumab)

Facing metastatic melanoma is not easy. It takes courage and commitment. As you begin your voyage with YERVOY (ipilimumab), you’ll likely have questions. That’s why we created the Your Voyage® Patient Support Program. The Your Voyage® Program will provide you with helpful information and resources to support you throughout your treatment journey. This comprehensive program consists of a series of educational mailings and live phone support. It’s all designed to help you better understand and take an active role in your treatment with YERVOY.

In this brochure, you’ll learn more about YERVOY and the Your Voyage® Patient Support Program. We hope you find it a source of helpful information and support as you begin your treatment journey.

Learn how the Your Voyage® Patient Support Program can help you. See page 16 for program details and how to sign up.

Please see Important Safety Information, including Boxed WARNING regarding immune-mediated side effects, on pages 14-15.
WHAT IS YERVOY (ipilimumab)?

YERVOY (ipilimumab) is a prescription medicine used in adults to treat melanoma (a kind of skin cancer) that has spread (metastatic) or cannot be removed by surgery (unresectable).

It is not known if YERVOY is safe and effective in children less than 18 years of age.

HOW YERVOY IS THOUGHT TO WORK

Our immune system helps protect us from disease. It has an army of T cells that seek out and destroy invaders such as melanoma. Sometimes, for many reasons, the T-cell army doesn’t fight as strongly as it should, or can’t fight as effectively against unresectable or metastatic melanoma cells.

YERVOY works through your immune system. YERVOY does not kill melanoma directly. Instead, YERVOY helps to rally the troops, and may get the T cells back in the battle against melanoma.

YERVOY may not work in all patients and may affect healthy cells too, which could result in serious side effects in many parts of your body. Some of these side effects may lead to death. Talk to your doctor about any questions you may have about YERVOY.
YERVOY (ipilimumab) CLINICAL TRIAL RESULTS

In a clinical trial, unresectable or metastatic melanoma patients were previously treated with one or more of the following: aldesleukin, dacarbazine, temozolomide, fotemustine, or carboplatin.

Clinical trial results showed that YERVOY (ipilimumab) patients lived substantially longer than patients who did not receive YERVOY. YERVOY will not work for every patient. Individual results will vary. It is important for patients to ask their doctors if YERVOY is right for them.

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How were patients treated in the YERVOY (ipilimumab) study? Of the 676 patients with unresectable or metastatic melanoma who participated in this trial: 20% or 137 patients received YERVOY alone, another 20% or 136 patients received another experimental drug alone, and 60% or 403 patients received YERVOY along with the experimental drug.

What was the goal of the YERVOY study? The major goal was to measure how long patients lived with YERVOY in combination with the experimental drug compared to the experimental drug alone.

What were the results of the study? Patients who received YERVOY alone and patients who took YERVOY plus another experimental drug showed a median* overall survival of 10 months. Patients who took the experimental drug alone showed a median overall survival of 6 months.

Over the course of the study, treatment with YERVOY decreased the risk of death by about one third compared to patients who received the experimental drug alone.

Based on the published results of this study, it is estimated that:
• 46% of metastatic melanoma patients taking YERVOY (ipilimumab) alone were alive at year 1 vs 25% of patients taking the experimental drug alone
• 24% of patients taking YERVOY alone were alive at year 2 vs 14% of patients taking the experimental drug alone

What are the serious side effects of YERVOY? YERVOY can cause serious side effects in many parts of your body which can lead to death. These serious side effects may include inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis; inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work; and inflammation of the eyes.

The most common side effects of YERVOY are tiredness, diarrhea, itching, and rash.

When may side effects appear? Side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion.

What should you do if you have side effects? Call your healthcare provider if you have any signs or symptoms or they get worse. Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed.

Do not try to treat symptoms yourself. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with YERVOY. Your oncologist may decide to delay or stop YERVOY. These are not all of the possible side effects of YERVOY. Please see Medication Guide for additional information. If you have any questions about your health or medicines, talk to your healthcare provider.

Please see Important Safety Information, including Boxed WARNING regarding immune-mediated side effects, on pages 14-15.
RECEIVING YERVOY (ipilimumab)

What should I tell my healthcare provider before getting YERVOY (ipilimumab)?
Tell your healthcare provider about all your health problems if you:
• have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn's disease, lupus, or sarcoidosis
• have an organ transplant, such as a kidney transplant
• have liver damage from diseases or drugs
• have any other medical conditions
• are pregnant or plan to become pregnant. YERVOY may cause stillbirth, premature delivery, and/or death of your unborn baby
• are breast-feeding. It is advised that nursing mothers do not breast feed while taking YERVOY
Tell your healthcare provider about all the medicines you take, including all prescription and non-prescription medicines, steroids or other medicines that lower your immune response, vitamins, and herbal supplements.
Know the medicines you take. Keep a list to show your doctors and pharmacists each time you get a new medicine. You should not start a new medicine before you talk with the healthcare provider who prescribes you YERVOY.

How do I receive YERVOY (ipilimumab)?
You'll receive YERVOY as an infusion in your vein. Typically, you'll get one dose every three weeks for up to 4 doses. It takes about 90 minutes to get a full dose. Your healthcare provider may change how often you receive YERVOY or how long the infusion may take. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with YERVOY. It is important for you to keep all your appointments with your healthcare provider. Call your healthcare provider if you miss an appointment. There may be special instructions for you.

What are scans and when will I get them?
Doctors use scans to check the growth or shrinkage of tumors. In the YERVOY (ipilimumab) study, scans were done at 12 and 24 weeks and then every 3 months. If a patient's tumor had shrunk at 12 or 24 weeks, they were scanned again at 16 or 28 weeks, respectively, to confirm if YERVOY was working.

What is the most important information I should know about YERVOY (ipilimumab)?
YERVOY can cause serious side effects in many parts of your body which can lead to death. These side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion. See the chart on page 12 to learn more.

Call your healthcare provider if you have any side effects or they get worse. Do not try to treat symptoms yourself. Getting medical treatment right away may keep the problem from becoming more serious. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with YERVOY. Your oncologist may decide to delay or stop YERVOY.

Please see detailed Important Safety Information, including Boxed WARNING regarding immune-mediated side effects, on pages 14-15.
### RECEIVING YERVOY (ipilimumab) (continued)

#### How will I know if I'm having side effects from YERVOY (ipilimumab)?

<table>
<thead>
<tr>
<th>Watch for the following symptoms:</th>
<th>These symptoms may be a sign of:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea (loose stools) or more bowel movements than usual; blood in your stools or dark, tarry, sticky stools; stomach pain (abdominal pain) or tenderness</td>
<td>Inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines</td>
</tr>
<tr>
<td>Yellowing of your skin or the whites of your eyes; dark urine (tea colored); nausea or vomiting; pain on the right side of your stomach; bleeding or bruise more easily than normal</td>
<td>Inflammation of the liver (hepatitis) that can lead to liver failure</td>
</tr>
<tr>
<td>Skin rash with or without itching; sores in your mouth; your skin blisters and/or peels</td>
<td>Inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis)</td>
</tr>
<tr>
<td>Unusual weakness of legs, arms, or face; numbness or tingling in hands or feet</td>
<td>Inflammation of the nerves that can lead to paralysis</td>
</tr>
<tr>
<td>Persistent or unusual headaches; unusual sluggishness, feeling cold all the time, or weight gain; changes in mood or behavior such as decreased sex drive, irritability, or forgetfulness; dizziness or fainting</td>
<td>Inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work</td>
</tr>
<tr>
<td>Blurry vision, double vision, or other vision problems; eye pain or redness</td>
<td>Inflammation of the eyes</td>
</tr>
</tbody>
</table>

These are not all of the possible side effects of YERVOY. Please see the Medication Guide for additional information.

If you have any questions about your health or medicines, talk to your healthcare provider.
IMPORTANT SAFETY INFORMATION
ABOUT YERVOY (ipilimumab)

YERVOY (ipilimumab) can cause serious side effects in many parts of your body which can lead to death. These serious side effects may include: inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines; inflammation of the liver (hepatitis) that can lead to liver failure; inflammation of the skin that can lead to severe skin reaction (toxic epidermal necrolysis); inflammation of the nerves that can lead to paralysis; inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work; and inflammation of the eyes.

These side effects are most likely to begin during treatment; however, side effects can show up months after your last infusion. Your healthcare provider should perform blood tests, such as liver and thyroid function tests, before starting and during treatment with YERVOY. Your oncologist may decide to delay or stop YERVOY. Call your healthcare provider if you have any signs or symptoms or they get worse. Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed. Do not try to treat symptoms yourself.

SERIOUS SIDE EFFECTS MAY INCLUDE:

• Inflammation of the intestines (colitis) that can cause tears or holes (perforation) in the intestines. 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
  ° stomach pain (abdominal pain) or tenderness

• Inflammation of the liver (hepatitis) that can lead to liver failure. Signs and symptoms of hepatitis may include:
  ° yellowing of your skin or the whites of your eyes
  ° dark urine (tea colored)
  ° nausea or vomiting
  ° pain on the right side of your stomach
  ° bleeding or bruise more easily than normal

• Inflammation of the nerves that can lead to paralysis. Symptoms of nerve problems may include:
  ° unusual weakness of legs, arms, or face
  ° numbness or tingling in hands or feet

• Inflammation of hormone glands (especially the pituitary, adrenal, and thyroid glands) that may affect how these glands work. Signs and symptoms that your glands are not working properly may include:
  ° persistent or unusual headaches
  ° unusual sluggishness, feeling cold all the time, or weight gain
  ° changes in mood or behavior such as decreased sex drive, irritability, or forgetfulness
  ° dizziness or fainting

• Inflammation of the eyes. Symptoms may include:
  ° blurry vision, double vision, or other vision problems
  ° eye pain or redness

PREGNANCY AND NURSING:

• Tell your healthcare provider if you are pregnant or plan to become pregnant. YERVOY (ipilimumab) may cause stillbirth, premature delivery, and/or death of your unborn baby. Before starting YERVOY, tell your healthcare provider if you are breast-feeding. It is advised that nursing mothers do not breast feed while taking YERVOY.

TELL YOUR HEALTHCARE PROVIDER ABOUT:

• Your health problems if you:
  ° have an active condition where your immune system attacks your body (autoimmune disease), such as ulcerative colitis, Crohn’s disease, lupus, or sarcoidosis.
  ° had an organ transplant, such as a kidney transplant
  ° have liver damage from diseases or drugs
  ° have any other medical conditions

• All the medicines you take including:
  ° all prescription and non-prescription medicines
  ° steroids or other medicines that lower your immune response
  ° vitamins
  ° herbal supplements

You should not start a new medicine before you talk with your healthcare provider who prescribes you YERVOY.

MOST COMMON SIDE EFFECTS:

The most common side effects of YERVOY (ipilimumab) include:

• tiredness
• diarrhea
• itching
• rash.

These are not all of the possible side effects of YERVOY. If you have any questions about your health or medicines, talk to your healthcare provider.

Please see accompanying Full Prescribing Information, including Boxed WARNING regarding immune-mediated side effects, and Medication Guide for YERVOY.

Please see accompanying Full Prescribing Information, including Boxed WARNING regarding immune-mediated side effects, and Medication Guide for YERVOY.
As you start treatment with YERVOY (ipilimumab), you may be asking yourself: What’s ahead for me? What information do I need to know? Where do I go from here? Where will this journey take me?

Bristol-Myers Squibb has created a special program for patients with unresectable or metastatic melanoma who are on or are considering YERVOY therapy—the Your Voyage® Patient Support Program. The program is designed to help you understand what to expect from YERVOY therapy, and to enhance discussions with your healthcare provider.

Your Voyage® gives you helpful resources and information you can relate to. It also explains possible side effects and the importance of reporting them early. This is because YERVOY (ipilimumab) can cause serious side effects in many parts of the body which can lead to death. Your Voyage® is an important part of your treatment journey—one that may help you to take a more active role in your therapy.

Once you join, you’ll get support in the form of education and information about YERVOY, downloadable resources, and more. And all of this support is designed to help you to better understand your treatment, potential benefits and side effects, and the importance of having an ongoing dialogue with your healthcare team.

Sign up to become a “Voyager,” and receive support information, delivered by mail, e-mail, and available online at www.YERVOY.com. You can also call 1-855-4YERVOY (1-855-493-7869).

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MEET THE VOYAGERS

Included throughout this brochure are examples of patients who could learn from the Your Voyage® Patient Support Program. Although these are not actual patients, they represent the types of people who may be on treatment with YERVOY (ipilimumab). Through the words and thoughts that appear throughout this brochure, we hope you’ll gain insight into what it’s like to be a YERVOY Voyager.

VOYAGER

JEFF

• Diagnosed 3 months ago with metastatic melanoma
• Failed dacarbazine

Hey Dad,

Thanks for your call and concern. I’m e-mailing instead of calling you back because it’s easier for me right now. I’ve been even more concerned lately since my last treatment didn’t work. So now we’re just trying to figure out next steps.

My doctor told me about a few treatment options that are available. One treatment option I’m considering sounds intriguing. It’s called YERVOY (ipilimumab). My doctor did tell me that reporting side effects right away with YERVOY would be very important—even after I’m done with treatment.

I’ve been spending a lot of time online trying to learn all that I can. There are some great resources out there, and they’ve helped a lot. I’ve also connected with some other people going through the same thing that I am. It’s great to know that I’m not alone, and have some extra support.

I’m still not sure what my next step will be, but the support of Kate, friends and family like you has really helped me through the past few days. I’ll be a little more relieved after my doctor and I figure out the right treatment for me.

Well that’s the scoop. Thanks so much for calling—and thanks even more for caring.

Jeff
VOYAGER

LINDA

- Diagnosed 1 month ago with metastatic melanoma
- About to receive first treatment of YERVOY (ipilimumab)

Dear Paul,

Hi sweetheart. Here’s my weekly letter…this time with a confession. I know you ask me if I am talking to my doctor about my diagnosis, but I have to admit, I haven’t done that yet. Before you pick up the phone and call me to give me a piece of your mind about this, let me explain.

It has been very difficult for me to accept my diagnosis of metastatic melanoma. I’ve been talking with my doctor about a treatment called YERVOY. My doctor told me that YERVOY may be appropriate for me. She also gave me lots of information to help me understand my therapy and possible side effects. This way I can report side effects if they should occur. But I need your support.

My dear son, I am hoping you can help me. I want to take good care of myself, but I need some help right now. I know you are busy with work, but would you come with me to my next doctor’s appointment and be there while I talk to my doctor and help me ask the right questions?

All my love,
Mom

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Robert

- Diagnosed 7 months ago with unresectable melanoma
- Failed temozolomide
- Received 3 YERVOY (ipilimumab) treatments
- Discontinued prior to fourth dose due to side effects

Honey:

I have been wanting to thank you for everything you’ve done for me over the years—especially now, since this diagnosis of unresectable melanoma. But you know me. It’s easier to write it than to say it.

I know I don’t tell you often enough how amazing you are. I admit I can be difficult at times—to say the least. You are a trooper for putting up with me. This disease has thrown me for a loop, what with chemo not working and now getting taken off YERVOY because of my side effects. My diarrhea became so severe, my doctor took me off of YERVOY. But having you there helped me through my treatment.

So, even though I can’t continue with YERVOY, I am grateful that you and I are together. Thank you for who you are and for everything you do every day. I love you.

Your loving (but still stubborn!) husband,
Bob

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Access Support®, the Bristol-Myers Squibb Oncology reimbursement services program is designed for health care professionals and their reimbursement office staff. It offers patient assistance support, benefits investigation, prior authorization support and appeals assistance. Please reach out to your oncologist for more information on these Bristol-Myers Squibb services. They can find more information at www.bmsaccesssupport.com.

The BMS Oncology Co-Pay Program

The BMS Oncology Co-Pay Program can assist eligible patients who have commercial (private) insurance.

HOW TO ENROLL

Talk to your oncologist or another healthcare team member to see if you are eligible. Your oncologist’s office can find more information at www.bmsaccesssupport.com and may be able to assist you with the enrollment process.

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DISCOVER THE YERVOY (ipilimumab) COMMUNITY

For additional support and encouragement, visit YERVOYCommunity.com. The YERVOY (ipilimumab) Community is an online community where you can watch videos of other patients sharing their experiences with melanoma (a kind of skin cancer) that has spread (metastatic) or cannot be removed by surgery (unresectable). And you can sign up to receive updates that we’ll send you when new information is available on the site. Go online now to visit YERVOYCommunity.com

While you’re reading and researching your disease, consider the community another resource. It can be a great source of support as you continue along your treatment journey.

Want more resources or to sign up for the Your Voyage® Patient Support Program?

Go to YERVOY.com

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If you no longer want to receive patient support materials, please call 1-888-308-8270 or visit www.YERVOY.com/unsubscribe

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