

YOUR CAREGIVER GUIDE TO BAVENCIO[®] (avelumab)

For treatment of certain patients with
advanced urothelial carcinoma (UC)

All portrayals are not actual patients.

INDICATIONS

BAVENCIO is a prescription medicine used to treat a type of cancer in the bladder or urinary tract called urothelial carcinoma (UC) when it has spread or cannot be removed by surgery (advanced UC). BAVENCIO may be used as maintenance treatment when your cancer has responded or stabilized after you have received platinum-containing chemotherapy as your first treatment or when you have received platinum-containing chemotherapy, and it did not work or is no longer working. It is not known if BAVENCIO is safe and effective in children under the age of 12.

SELECTED SAFETY INFORMATION

BAVENCIO[®] (avelumab) is a medicine that may treat certain cancers by working with your immune system. BAVENCIO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please see Important Safety Information on pages 14 to 17.
Click for full [Prescribing Information](#) and [Medication Guide](#) or visit bavencio.com.

 **BAVENCIO[®]**
avelumab Injection
20 mg/mL

HOW CAN THIS GUIDE ASSIST YOU AS A CAREGIVER?

Learning that someone you care about has advanced urothelial carcinoma (UC) can be difficult to hear and process. For both you and the one you're caring for, it can be a life-changing event. Now, more than ever, your loved one may need your support as a caregiver.

This guide is designed to help you:

- Better understand what to expect and the importance of your role
- Get the kind of information and support you need to provide care, as well as care for yourself

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**REMEMBER—THIS GUIDE
DOESN'T REPLACE MEDICAL CARE
OR ADVICE FROM A DOCTOR**

It's important to work with your loved one's healthcare team and ask them any questions you may have.

Caregiving and advanced UC

What is my role as a caregiver of someone with advanced UC?

Your support can be helpful to your loved one as they are treated for advanced UC. Perhaps you've already discovered that while caregiving can sometimes be challenging, it can also be rewarding to help your loved one.

Your role may include:

- ✓ Providing both physical and emotional support
- ✓ Managing everyday tasks, such as meals, laundry, and insurance claims
- ✓ Arranging medical appointments and accompanying the one you care for to their visits
- ✓ Assisting with treatment and other medical decisions
- ✓ Providing transportation to the doctor, treatment facility, or even to the grocery store

THE SUPPORT YOU MAY PROVIDE AT HOME CAN BE AN IMPORTANT ADDITION TO THE CARE THAT HAPPENS AT THE DOCTOR'S OFFICE

About urothelial carcinoma (UC)

What is UC?

Most bladder cancers develop in the innermost lining of the bladder, called the urothelium. If the cancer grows into the other layers of the bladder wall, it becomes more advanced and can be harder to treat.

UC develops in cells of the urinary system. While 90% of UC is found in the bladder, UC may also occur in parts of the kidney, ureter, or urethra.

What is locally advanced or metastatic UC?

Over time, cancers such as UC can spread throughout your body.

When tumors spread to nearby tissue or lymph nodes, it is called **locally advanced**. When tumors spread to other parts of your body, it's called **metastatic**.

How common is locally advanced and metastatic UC?

Bladder cancer is the sixth most common cancer in the United States, with approximately 80,000 new diagnoses a year.

UC is the most common type of bladder cancer. In fact, almost 90% of all bladder cancers are UC. Of those, approximately 12% of patients (about 8,600) are diagnosed with either locally advanced or metastatic UC.

Advanced UC can impact your loved one's emotional health

The person you're caring for may experience a range of different emotions

- Whether it's from having advanced UC or receiving treatment for it, it's normal for the one you support to have good and bad days and experience a roller coaster of emotions. Having advanced UC can impact their mood, personality, or outlook and they may need time to adjust to the changes in their life
- Try to not take it personally when your loved one gets upset or frustrated
- Reinforce to your loved one that having advanced UC is not their fault

Your emotional support is key

- One of the most important things you do as a caregiver may be providing emotional support. It starts with being well informed about their cancer and treatment
- The more you know, the better you can understand what's involved and how to help the one you're caring for cope and live as normal a life as possible
 - Be sure to ask the healthcare team lots of questions about your loved one's cancer, the treatment and care involved, and what to expect as time goes on

Good communication matters

- Make sure that the person you're caring for knows that you are always open to talking and listening, even about tough subjects, which could include their physical well-being, relationships, social life, and possible changes in intimate parts of their body
- At the same time, it's important that you respect their need to either share their feelings or to remain quiet. Find out what works best for both of you. And don't be afraid to ask for advice from others, especially the healthcare team
- You are not alone. Talking with other caregivers may help. There are support and advocacy groups that you can join listed on page 26

REMEMBER—WHILE PROVIDING EMOTIONAL SUPPORT HAS MANY REWARDS, THERE MAY BE TIMES WHEN YOU FEEL OVERWHELMED AND AT RISK OF STRESS, BURNOUT, AND ANXIETY

It may be helpful to talk to a mental health professional.





DO YOU HAVE CONCERNS OR QUESTIONS ABOUT YOUR LOVED ONE'S TREATMENT WITH BAVENCIO®?

Write them down as you may wish to share them during the next doctor's visit.

Here are examples of some questions you may want to ask your loved one's healthcare team:

- How can I help my loved one prepare for their treatment?
- How could my loved one's treatment help?
- What can I do to make my loved one more comfortable?
- What are the side effects of my loved one's treatment?

Write down any other questions you can think of below:

BAVENCIO maintenance treatment

Understanding your loved one's treatment

Why is platinum-containing chemotherapy usually the first treatment given?

- Platinum-containing chemotherapy consists of cancer drugs that travel through the bloodstream to kill cancer cells or stop them from dividing. Platinum-containing chemotherapy has been the recommended treatment for advanced UC for over 20 years

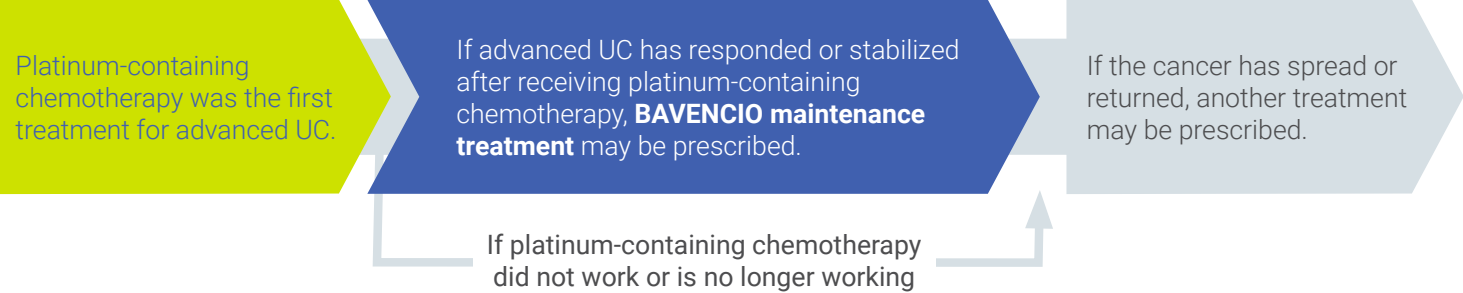
After chemotherapy, what can BAVENCIO® (avelumab) maintenance treatment do?

- If the tumor responded or stabilized following platinum-containing chemotherapy, BAVENCIO, an immunotherapy, may help the immune system fight cancer cells.

When can BAVENCIO® (avelumab) maintenance treatment be prescribed?

BAVENCIO® (avelumab) maintenance treatment may be an important part of your loved one's treatment plan

See the chart below to help you understand when BAVENCIO may be prescribed.



Infusion treatment days

BAVENCIO® (avelumab) is administered by a doctor or a nurse in an infusion center, hospital, or doctor's office



Intravenous
infusion (IV)



Over 60
minutes



Every
2 weeks

What can I do to help?



SCHEDULE THE APPOINTMENTS

What do you do if your loved one misses any appointments?

Call their healthcare provider as soon as possible to reschedule their appointment



ARRANGE FOR TRANSPORTATION

- If possible, plan to accompany your loved one to the infusion center or clinic, or arrange for a friend or family member to cover for you
- Arrange to drive or provide alternate transportation



MAKE THE MOST OF YOUR TIME AT THE INFUSION CENTER OR CLINIC

- Consider bringing a book, tablet, or your favorite music to pass the time
- Some other items you might find useful to bring are a notebook, pen, calendar, water bottle, and blanket
- Ask the doctor or nurse any questions you may have and discuss any concerns you're feeling

IMPORTANT SAFETY INFORMATION

BAVENCIO® (avelumab) is a medicine that may treat certain cancers by working with your immune system. BAVENCIO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

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

BAVENCIO can cause serious side effects. Call or see your healthcare provider right away if you get any new or worsening signs or symptoms, including:

Lung problems

- cough
- shortness of breath
- chest pain

Intestinal problems

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

Liver problems

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

Hormone gland problems

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

Kidney problems

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

Skin problems

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

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

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

Continued on next page

IMPORTANT SAFETY INFORMATION (cont'd)

Infusion-related reactions can sometimes be severe or life-threatening. Signs and symptoms of infusion-related reactions may include:

- chills or shaking
- hives
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back pain
- stomach-area (abdomen) pain

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

Before you receive BAVENCIO, tell your healthcare provider about all of your medical conditions, including if you:

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

Females who are able to become pregnant:

- You should use an effective method of birth control during your treatment and for at least 1 month after the last dose of BAVENCIO. Talk to your healthcare provider about birth control methods that you can use during this time

- are breastfeeding or plan to breastfeed. It is not known if BAVENCIO passes into your breast milk. Do not breastfeed during treatment and for at least 1 month after the last dose of BAVENCIO.

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

The most common side effects of BAVENCIO as maintenance treatment in people with urothelial carcinoma (UC) whose cancer responded or stabilized after platinum-containing chemotherapy as first treatment include:

- feeling tired
- muscle and bone pain
- urinary tract infection
- rash

The most common side effects of BAVENCIO in people with UC after platinum-containing chemotherapy that did not work, or is no longer working, include:

- feeling tired
- infusion-related reactions including chills, fever, back pain, redness, and shortness of breath
- muscle and bone pain
- nausea
- decreased appetite
- urinary tract infection

These are not all the possible side effects of BAVENCIO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Please see full [Prescribing Information](#), including [Medication Guide](#) for patients.

WHAT SHOULD I DO IF THE PERSON I'M CARING FOR HAS A SIDE EFFECT?

Remember—It's important to tell the doctor about any side effect, including inflammation, the one you're caring for experiences while on BAVENCIO. And don't wait! The doctor can help manage side effects.

Tips to help manage certain side effects

Not all side effects are manageable. If your loved one is having side effects, your doctor may decide to adjust or stop their treatment. That's why it's important to tell the doctor right away about ANY side effect your loved one is experiencing while taking BAVENCIO® (avelumab). You can find a list of possible serious side effects in the Important Safety Information starting on page 14 of this brochure.

Here are some general tips that may help to manage certain side effects, based on published guidance, and are not specific to treatment with BAVENCIO.

Always remember: Before your loved one makes any changes to their diet, physical activity, or treatment plan, please ensure they consult with their doctor.



Feeling tired

While on treatment, your loved one may feel tired. Call the doctor for a full evaluation if they experience fatigue. **Talk with your loved one's doctor if tiredness is a recurring problem. The doctor may recommend that they:**

- Take short naps and breaks instead of long ones
- Eat well and drink plenty of fluids
- Stay physically active or introduce moderate physical activities
- Try to maintain normal work and social schedules

Talk to the doctor about the ways to help manage your loved one's fatigue.



Muscle and bone pain

While on treatment, your loved one may experience new or worsening muscle or bone pain. The pain may be in a specific area or may be more widespread. **Talk with the doctor if your loved one experiences any muscle or bone pain. The doctor may recommend that they:**

- Take medications, if the doctor prescribes them for your loved one
- Try massage or physical therapy
- Use hot or cold compresses

Talk to the doctor about the pain relief that may be right for your loved one.



Urinary tract infection (UTI)

While on treatment, your loved one may experience signs and symptoms of a UTI, such as a burning feeling when they urinate, back pain, or fever. **Call the doctor if your loved one experiences any signs or symptoms of a UTI. The doctor may recommend that they:**

- Take medications, if the doctor prescribes them for your loved one
- Drink plenty of liquids
- Go to the bathroom often
- Take showers instead of baths
- Wear cotton underwear and loose fitting pants

Talk to the doctor about the steps to manage and prevent UTIs.



Rash

While on treatment, your loved one may experience skin rashes on various parts of the body. Rashes can present in different ways such as flat or raised bumps or different colors. Rashes can also itch, burn, sting, or be painful. **Talk with the doctor if your loved one experiences signs and symptoms of a rash. The doctor may recommend that they:**

- Take medications, if the doctor prescribes them for your loved one
- Use mild soaps and encourage your loved one to keep their skin moisturized with cream-based moisturizers
- Protect the affected area from heat and cold and wear loose-fitting, soft clothing
- Minimize sun exposure and use sunscreen

Talk to the doctor about the steps to relieve rash that may be right for your loved one.

BAVENCIO can cause serious side effects, including: lung problems, intestinal problems, liver problems, hormone gland problems, kidney problems, skin problems, other immune system problems, infusion-related reactions, and complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). Please see pages 14 to 17 for more information on possible serious side effects.

Questions for the doctor

As a caregiver, you may attend some medical appointments with the one you're caring for. When you meet with the doctor or other members of the healthcare team, it's important that you ask questions about your loved one's advanced UC and their BAVENCIO® (avelumab) maintenance treatment.

- › What can be expected during treatment?
- › How is this different from chemotherapy?
- › How will we know if the treatment is working?
- › Is there anything we should eliminate from the diet or avoid altogether?
- › What are common side effects of the medicine? Do you have any tips to help manage them?
- › Whom do we contact if side effects occur?
- › What support resources are available?
- › How can we apply for financial assistance? Are there any services or programs we could learn about?

Other questions or concerns I'd like to remember

Make note of them here so you can get them answered or discussed at the next appointment.

Taking care of me

By taking care of yourself, you can provide better care

- Many caregivers say they feel a sense of satisfaction in their role of caring for their loved one. At the same time, it can sometimes be physically and emotionally draining. And, all too often, caregivers are so busy focusing on the care of the other person that they place their own physical and emotional needs on hold
- As other caregivers have found out, if you don't take care of yourself, you may have a hard time taking care of someone else

REMEMBER—IT'S IMPORTANT THAT YOU STAY HEALTHY, PHYSICALLY AND MENTALLY, FOR BOTH OF YOU!

What are some things I can do?

**BRING ON
BAVENCIO**

zzz...



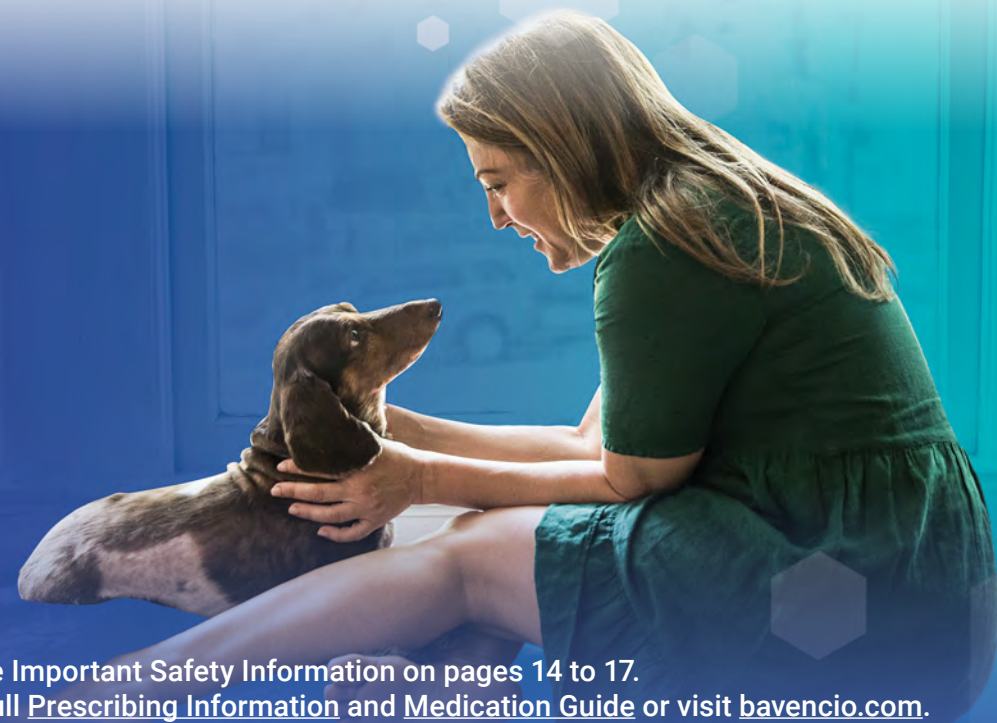
Before making any changes to your diet, physical activity, or medications, always consult with your doctor.

BAVENCIO
avelumab Injection
20 mg/mL

What are some ways to help deal with burnout and stress?

What's burnout?

- Burnout is emotional, physical, and mental exhaustion. You may feel overwhelmed and unable to meet the constant demands on your time, energy, or even your financial resources. **Burnout can happen with prolonged stress, which can come with being a caregiver for someone with advanced UC**



Tips on managing burnout



SCHEDULE REGULAR BREAKS DURING THE DAY

so you can give yourself time to restore your energy and positive outlook



DO SOMETHING YOU ENJOY,

such as meeting up with a friend, watching a movie, listening to music, or even reading a book



GETTING OUTSIDE

for a quick walk or even to garden can help relieve stress



TAKE A DAY OFF FROM CAREGIVING,

which means asking if someone can stay with the person you're caring for to help lighten your burden



EXPRESSING HOW YOU FEEL

with a close friend or family member can help ensure that negative emotions or concerns don't get bottled up



JOIN A SUPPORT GROUP

so that you can connect with other caregivers in similar situations who can share how they deal with burnout and stress

Where can I find support and connect with caregivers?

- There are many groups and organizations that can help caregivers find the support they need. Explore these online resources to help you stay informed about advanced UC, connect with other caregivers, and learn more about caring for yourself

Learn more about urothelial carcinoma, connect with others, and get information and support from these helpful organizations



American Cancer Society
www.cancer.org/treatment/caregivers.html



Bladder Cancer Advocacy Network
www.bcan.org/find-support/caregiver-resources



Bladder Cancer Patient Support Group
www.cancercare.org/tagged/caregiving

The organizations listed above are independent nonprofit organizations. Their inclusion here does not imply endorsement of BAVENCIO® (avelumab) or EMD Serono, Inc.

EMD Serono, Inc. is not responsible for the content on their respective websites.

Important contact information

Now, more than ever, it's important to be super organized and save time whenever you can

Use this page to write down the healthcare team's contact information so you have it handy for quick and easy access.

Doctor

Address

Phone

Email

Other healthcare team member

Address

Phone

Email

What are some potential financial responsibilities?

Like many caregivers, you may have to manage finances for the one you support

- This new financial responsibility may include the management of medical bills and insurance claims. Some caregivers decide to rearrange their work schedule or even take some time off to meet the demands of being a caregiver

Learn about financial assistance

- Don't hesitate to reach out to a financial counselor either in the doctor's office or at the local hospital to get advice and assistance. Ask about patient support programs that may help cover some of the expenses for the person you're caring for

**ALWAYS REMEMBER,
YOU'RE NOT ALONE**

Navigating your role as a caregiver can leave you with many questions. Consider joining a support group with caregivers in similar situations who can share their experience. (Please see page 26 for some helpful links.)

CoverOne® provides patient access and reimbursement support

**BRING ON
BAVENCIO**

We recognize that each patient's situation is different and are dedicated to helping eligible BAVENCIO® (avelumab) patients one at a time

Please contact us at **1-844-8COVER1** if you have any questions.

CoverOne®

CoverOne® provides eligible BAVENCIO patients access and reimbursement support services.*

*Eligibility requirements and restrictions may apply.



Phone: 1-844-8COVER1
(1-844-826-8371)
Monday–Friday
8:00 AM–8:00 PM ET



Fax: 1-800-214-7295



Web: CoverOne.com

LEARN MORE AT **BAVENCIO.COM**

Click for full [Prescribing Information](#) and [Medication Guide](#) or visit bavencio.com.

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SERONO**

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US-AVE-01621 06/24

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