

# Your Guide to Treatment With **BAVENCIO**<sup>®</sup> (avelumab)

## INDICATION

BAVENCIO is a prescription medicine used to treat a type of skin cancer called Merkel cell carcinoma (MCC) in adults and children 12 years of age and older. BAVENCIO may be used when your skin cancer has spread. This indication is approved under accelerated approval based on a clinical trial that measured how many patients responded and how long they responded. Continued approval may depend on benefit demonstrated in ongoing clinical trials. It is not known if BAVENCIO is safe and effective in children under the age of 12.

Please see Important Safety Information on pages 6-7. Click for the full [Prescribing Information and Medication Guide](#), or visit [BAVENCIO.com](https://www.bavencio.com).

# Merkel cell carcinoma, or MCC, is a rare skin cancer that can spread quickly



## How common is MCC?

Of the about 2,500 Americans diagnosed with MCC each year, approximately 10% of them will have metastatic disease at diagnosis.

For comparison, over 80,000 Americans are diagnosed with melanoma, a more common skin cancer, each year.



## What does MCC look like?

Tumors are usually firm, painless, and grow quickly. They are often red or purple.



## Where does MCC usually start?

MCC usually develops on areas of the skin that are exposed when you are outside, such as your head, neck, arms, and legs.



## What is metastatic MCC?

Over time, cancers such as MCC can spread to other parts of your body.

When additional tumors appear or existing ones spread, the process is called metastasis, and the new tumors are called metastases.



## How is MCC diagnosed?

If your doctor suspects that a mole or skin tumor might be cancerous, a procedure called a biopsy can be used to find out for sure.

To do a biopsy, your doctor removes some or all of the suspicious mole or tumor, and then sends it to a lab for testing.

In the lab, doctors use a variety of tests to find out if the sample is cancerous and, if it is, exactly what kind of cancer it is.



## How is MCC treated?

There are a number of ways to treat this type of cancer. Four common treatments are:

- **Surgery**, which removes cancer cells from the body
- **Chemotherapy**, which kills cancer cells
- **Radiation therapy**, which uses high-energy radiation on cancer cells
- **Immunotherapy**, which helps your immune system kill cancer cells

Your doctor may also consider whether a clinical trial is right for you.



## What makes it more likely that someone will get MCC?

People with a weakened immune system are more likely to develop MCC. For example, people who have a disease like leukemia or HIV/AIDS may have a weakened immune system. People who have received organ transplants may also have a weakened immune system.

Time in the sun increases the risk of developing MCC.

MCC is most common in older people (around age 75).

Having a Merkel cell polyomavirus infection can increase the risk of developing MCC, and although this infection is common, it mostly does not cause cancer.

# BAVENCIO® (avelumab) is an immunotherapy—a medicine that may help your immune system fight metastatic MCC

## BAVENCIO treats metastatic MCC

BAVENCIO is used after MCC has spread to other parts of your body, or metastasized.



BAVENCIO is a man-made antibody. Your body naturally produces antibodies to help your immune system work.



BAVENCIO is the first medicine that the Food and Drug Administration (FDA) approved to treat metastatic MCC in adults and children ages 12 and older.



BAVENCIO is delivered by an intravenous (IV) infusion directly into your bloodstream.

## BAVENCIO is the only FDA-approved immunotherapy that may engage both your adaptive and innate immune systems

The immune system is a part of your body that fights diseases to keep you healthy. One job of your immune system is to remove cells that are becoming cancerous. Over time, cancer cells may be able to stop your immune system from attacking them.

**Your adaptive immune system learns to identify and adapt to threats over time, and delivers a response to defend against specific threats**

**Your innate immune system is your first line of defense against general threats**

## What is the most important information I should know about BAVENCIO?

BAVENCIO 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.

## A clinical trial tested if BAVENCIO could help patients with MCC who had already received chemotherapy for cancer that had spread

**33%** of patients (29 of 88) in the trial saw their tumors get smaller

- 11% of patients (10 of 88) saw their tumors disappear (complete response)
- 22% of patients (19 of 88) saw their tumors shrink (partial response)

### Among patients whose tumors got smaller (29 of 88 patients)...

**86%** of cases (25 of 29 patients) had an ongoing effect for **at least 6 months**

**45%** of cases (13 of 29 patients) had an ongoing effect for **at least 1 year**

The minimum duration of this effect was 2.8 months and maximum duration of this effect was over 23.3 months.

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

# IMPORTANT SAFETY INFORMATION FOR BAVENCIO® (avelumab)

BAVENCIO 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 serious 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



**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 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 final 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 in people with Merkel cell carcinoma (MCC) include:

- feeling tired
- muscle and bone pain
- diarrhea
- nausea
- infusion-related reactions including chills, fever, and back pain
- rash
- decreased appetite
- swelling in your hands, feet, or ankles

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](http://www.fda.gov/medwatch).

Click for the full [Prescribing Information](#) and [Medication Guide](#), or visit [BAVENCIO.com](http://BAVENCIO.com).





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

**Your healthcare provider will give  
you BAVENCIO via IV infusion over  
60 minutes**

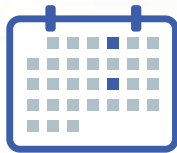
- Your healthcare provider will give you medicines (an antihistamine and acetaminophen) before the first 4 infusions and then as needed to help reduce infusion reactions
- BAVENCIO is usually given every 2 weeks
- Your healthcare provider will decide how many treatments you need
- Your healthcare provider will do blood tests to check you for certain side effects



**Intravenous  
infusion (IV)**



**Over 60  
minutes**



**Every  
2 weeks**

**Some resources that you may find helpful**

**Resources\***

**Skin Cancer Foundation:** <https://www.skincancer.org/skin-cancer-information/merkel-cell-carcinoma/>  
**merkelcell.org:** <https://merkelcell.org/>

**Support groups\***

**Seattle Support Group:** <https://sites.google.com/site/merkelcellcarcinomaseattle/home>  
**Merkel Cell Google Group:** <https://merkelcell.org/resources/get-support/>  
**Smart Patients Merkel Cell Group:** <https://www.smartpatients.com/>

\*These groups are not affiliated with EMD Serono, Inc., or Pfizer Inc. EMD Serono, Inc., and Pfizer Inc are not responsible for the content.

**Notes:**

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CoverOne® provides patient access and reimbursement support to help eligible patients gain appropriate access to BAVENCIO® (avelumab).\*

\*Eligibility requirements and restrictions may apply.

**We recognize that each patient's situation is different and are dedicated to helping eligible BAVENCIO patients one at a time.**

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

# CoverOne®

**PHONE:** 844-8COVER1 (844-826-8371)

**FAX:** 800-214-7295

**CoverOne.com**

Monday-Friday, 8:00 AM-8:00 PM ET

**Our mission is to advance the  
field of immuno-oncology and  
reimagine how we treat cancer.**

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