OPDIVO® will not work for everyone. Individual results may vary. Please see information about the clinical trial, including serious side effects, on pages 2-3.

**What is OPDIVO?**

OPDIVO is a prescription medicine used to treat people who have **head and neck cancer called squamous cell carcinoma of the head and neck (SCCHN)**, and who:

- Have been treated with chemotherapy that contains platinum, but their head and neck cancer has returned or spread after treatment.

**It is not known if OPDIVO is safe and effective in children younger than 18 years of age.**

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 Important Facts about OPDIVO, including serious side effects, on pages 7-8 and U.S. Full Prescribing Information and Medication Guide.
SUPERIOR SURVIVAL AT 1 YEAR with OPDIVO in a clinical trial

Learning that your cancer has come back or spread after enduring treatments like chemotherapy or radiation can be overwhelming. But even when those options have been unsuccessful, there may still be hope. Talk to your doctor about a different kind of treatment option—OPDIVO.

In a clinical trial of 361 people with previously treated squamous cell carcinoma of the head and neck, 240 people took OPDIVO and 121 people took standard therapy options.*

<table>
<thead>
<tr>
<th>AT 1 YEAR</th>
<th>AT 2 YEARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Based on 78% of the 361 people in the trial:</td>
<td>Based on all 361 people in the trial:</td>
</tr>
<tr>
<td>36% of people who took OPDIVO were alive</td>
<td>17% of people who took OPDIVO were alive</td>
</tr>
<tr>
<td>17% of people who took standard therapy options were alive</td>
<td>6% of people who took standard therapy options were alive</td>
</tr>
</tbody>
</table>

*Based on a two-year follow-up looking at survival for all 361 people at 1 year:
34% of people who took OPDIVO were alive
20% of people who took standard therapy options were alive

OPDIVO will not work for everyone. Individual results may vary.

*Standard therapy options include: cetuximab, methotrexate, or docetaxel.

What are the serious side effects of OPDIVO?

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.

- lung problems
- intestinal problems
- liver problems
- hormone gland problems
- kidney problems
- skin problems
- problems in other organs and tissues
- severe infusion reactions
- complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)

Please see additional Important Facts about OPDIVO, including these serious side effects, on pages 7–8 and U.S. Full Prescribing Information and Medication Guide.
A Chance to Live Longer
Proven in a clinical trial to significantly increase survival

Is OPDIVO right for me?
That’s a conversation you need to have with your oncologist. But you should know that OPDIVO is a different kind of treatment option that may work for you. OPDIVO is approved for adults whose SCCHN has returned or spread after treatment with platinum-based chemotherapy.

What are the most common side effects of OPDIVO?
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
- shortness of breath
- constipation
- decreased appetite
- back pain
- upper respiratory tract infection
- fever
- headache
- stomach-area (abdominal) pain
- urinary tract infection

These are not all of the possible side effects of OPDIVO. 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.

Half of the people who took OPDIVO were alive at 7.7 months compared to 5.1 months with standard therapy options at 2 years. When the study results were analyzed at one year, half of the people on OPDIVO were alive at 7.5 months versus 5.1 months with standard therapy options.

OPDIVO will not work for everyone. Individual results may vary.

*Standard therapy options include: cetuximab, methotrexate, or docetaxel.

Please see additional Important Facts about OPDIVO, including serious side effects, on pages 7–8 and U.S. Full Prescribing Information and Medication Guide.
What are head and neck cancers?

Many different types of cancer can occur in the head and neck. The most common is squamous cell carcinoma of the head and neck (SCCHN).

Most SCCHN begins in the layer of cells that line the moist surfaces inside the head and neck, for example the mouth—including the tongue, lips, or cheeks—throat, sinuses, and voice box. In some people, oral infection with human papillomavirus (HPV) can lead to HPV-positive squamous cell cancer of the mouth or pharynx.

Ask your doctor if OPDIVO may be right for you.

What should I discuss with my healthcare team before I start Opdivo?

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 can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO and for 5 months after the last dose of OPDIVO.

Females who are able to become pregnant:
Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.
- You should use an effective method of birth control during your treatment and for at least 5 months after the last dose of OPDIVO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO.

Tell your healthcare provider about all the medicines you take, including:

- prescription medicines
- over-the-counter medicines
- vitamins
- herbal supplements

Please see additional Important Facts about OPDIVO, including these serious side effects, on pages 7–8 and U.S. Full Prescribing Information and Medication Guide.
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 Helps active T cells identify cancer cells that are hiding.

ACTIVE T CELLS

With OPDIVO, more active T cells may be able to help seek and attack cancer 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. Please see pages 7-8 for a list of possible side effects and what to look out for.

Visit OPDIVO.com for more information.
The OPDIVO option: Offering a balance between treatment schedules and regular visits with your healthcare team

Talk to your doctor about which option is right for you

- every 2 weeks
  The opportunity for more regularly scheduled visits with your healthcare team

- or -
  every 4 weeks
  The confidence of regular visits with your healthcare team, but with more time between appointments

Infusion time: 30 minutes

1st scan at about Week 9
Continue treatment every 2 or 4 weeks as long as it is working and side effects are tolerable

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 about which treatment schedule may be right for you. 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.

See page 8 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 and the same time of day to make them easier to remember. It is important for you to keep all appointments with your healthcare provider.

Please see Important Facts about OPDIVO, including serious side effects, on pages 7-8 and U.S. Full Prescribing Information and Medication Guide.
Important Facts about OPDIVO® (nivolumab)

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

Look out for the following icons as you read:

Talk to your healthcare team

Call a healthcare provider right away

Helpful information to remember

What is OPDIVO?

OPDIVO is a prescription medicine used to treat people who have head and neck cancer called squamous cell carcinoma of the head and neck (SCCHN), and who:

☑ Have been treated with chemotherapy that contains platinum, but their head and neck cancer has returned or spread after treatment.

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

What is the most important information I should know about OPDIVO?

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work.

⚠️ 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?

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
• bleeding or bruising more easily than normal

Liver problems — Things to look out for may include:
• yellowing of your skin or the whites of your eyes
• severe nausea or vomiting
• pain on the right side of your stomach area (abdomen)
• dark urine (tea colored)

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
• swelling of your ankles
• loss of appetite

Skin problems — Things to look out for may include:
• rash
• itching
• painful sores or ulcers in the mouth or nose, throat, or genital area
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. 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?

OPDIVO can cause serious side effects, including:

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

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

Tell your healthcare team right away if you get these symptoms during an infusion of OPDIVO.

Complications of bone marrow (stem cell) transplant that uses donor stem cells (allogenic). 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. Your healthcare provider will monitor you for these complications.

What are the most common side effects of OPDIVO?

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
- shortness of breath
- constipation
- decreased appetite
- back pain
- upper respiratory tract infection
- fever
- headache
- stomach-area (abdominal) pain
- urinary tract infection

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

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 (allogenic)
- 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 can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO and for 5 months after the last dose of OPDIVO.

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Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.

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- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO.

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, or talk to your healthcare team.
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*

The Oral Cancer Foundation (OCF) oralcancer.org
OCF provides people with cancer and their caregivers access to a free, anonymous support group overseen by long-term survivors and oncology professionals. Their website provides information about the disease, treatment, and current research.

Head and Neck Cancer Alliance (HNCA) headandneck.org
HNCA is dedicated to saving lives and improving the quality of life for patients who have oral, head and neck cancer focusing on prevention, early detection, advocacy, patient programs, awareness, education, and research.

Support for People with Oral and Head and Neck Cancer (SPOHNC) spohnc.org
SPOHNC is dedicated to raising awareness and meeting the needs of oral and head and neck cancer patients through its resources and publications, which include support groups, a one-on-one matching program, and educational materials vital to one’s journey with this disease.

CancerCare cancercare.org
This site directs people with cancer and caregivers to a wide range of free counseling, support groups, education, and financial assistance services all over the country.

Cancer Support Community cancersupportcommunity.org
This organization provides emotional and educational services for all people affected by cancer.

National Brain Tumor Society braintumor.org
Today, the National Brain Tumor Society continues its legacy of driving research accomplishments and discoveries toward treatments, servicing, guiding, and preparing patients to face their disease, changing public policy agendas through country-wide advocacy, and providing a powerful voice that unites the brain tumor community.

*Bristol Myers Squibb does not endorse these organizations. The information/links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician’s medical advice.

Please see Important Facts about OPDIVO, including serious side effects, on pages 7–8 and U.S. Full Prescribing Information and Medication Guide.
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)

For more information, call 1-855-OPDIVO-1 or visit [www.OPDIVO.com](http://www.OPDIVO.com)

Please see Important Facts about OPDIVO, including serious side effects, on pages 7-8 and [U.S. Full Prescribing Information](http://www.OPDIVO.com) and [Medication Guide](http://www.OPDIVO.com).

Bristol Myers Squibb is committed to helping patients throughout their treatment.

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