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on immuno-
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therapies

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“I’m
reclaiming
my life!”

Advanced Kidney Cancer

Blindsided by a diagnosis of kidney cancer, lifelong fitness enthusiast Brandy Verdin was told she wasn't a candidate for surgery and should "just accept palliative care." Refusing to bow down, she turned to her faith and today is giving her cancer a one-two punch with a combination treatment that has her back in the game.

Health Monitor Living **Advanced Kidney Cancer**



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PES23

Cover photo by Scott Myers



Keep looking ahead!

With today’s treatment breakthroughs, there’s every reason to believe you can get the upper hand on your advanced kidney cancer.



These days, Stanley H. is focused on three things: his fishing game, his garden and spending time with grandson Theo. Not making that list? His advanced renal cell carcinoma.

After his diagnosis last year—triggered by symptoms including lower back pain and weight loss—Stanley was immediately put on a combined treatment featuring both an immuno-

therapy, which helps his body’s own immune system find and attack the cancer, as well as a targeted therapy, which works by blocking a protein cancer that cells need to multiply. The result? Since starting treatment, Stanley’s tumors have either shrunk completely or stabilized, meaning the cancer is no longer growing.

“I feel blessed that I was diagnosed at a time when stage IV cancer is no longer the death sentence it used to be. Hearing ‘you have cancer’ still changes your whole world, yet the follow-up: ‘but we can treat it!’ shifts everything back into focus!” ▶



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Every cancer. Every life.™

Where do you fit in?

Whether you've been newly diagnosed with advanced kidney cancer, your disease has progressed despite being treated or recurred following treatment, you have good reason to be as hopeful as Stanley. The latest treatments can stabilize and even eradicate the cancer, transforming advanced kidney cancer into a chronic illness that may be managed for years.

Ready to take aim at your cancer? Keep reading this guide, then discuss all your options with your oncologist.

Understanding kidney cancer

Your kidneys filter blood to remove impurities, excess minerals and salts, and extra water from the body. Kidney cancer develops when abnormal cells in the kidneys begin to multiply. Most often, a tumor forms in one kidney, although two or more tumors can develop in one or both kidneys.

The most common type of adult kidney cancer is renal cell carcinoma (RCC), accounting for nine in 10 cases. RCC develops in the renal tubules, the tubes that collect urine. There are different subtypes of RCC. Seventy percent

of people with RCC have clear cell renal cell carcinoma. Less common subtypes include papillary renal cell carcinoma and chromophobe renal cell carcinoma.

Because early RCC does not always cause obvious symptoms, the disease is often not detected until it is at an advanced stage: In stage III kidney cancer, the cancer has spread to lymph nodes near the kidney, a main kidney blood vessel, or fatty tissue around the kidney. In stage IV kidney cancer, the cancer has spread to another organ or to other lymph nodes or tissue. Signs and symptoms may include:

- Blood in the urine
- A mass or lump on your abdomen, your side or your lower back
- Persistent lower back pain or pressure on your side
- Loss of appetite
- Unexplained weight loss
- Anemia (low red blood cell count)
- Swollen ankles and legs
- Fatigue
- Persistent fever not caused by infection
- In men, enlarged veins around a testicle (i.e., varicocele)

How is advanced kidney cancer (RCC) detected?

To diagnose a case of kidney cancer that is already advanced, your doctor will ask about your symptoms, perform a physical exam and inquire about your personal and family medical history. Your doctor may also order blood and urine tests, as well as a biopsy, in which a tissue sample is removed and examined for malignant cells. To determine if cancer has spread, and where, your doctor may order one or more of the following imaging tests: a CT scan, MRI (magnetic resonance imaging), X-ray, ultrasound or bone scan.

How is advanced kidney cancer treated?

When determining your treatment plan, your oncologist will consider several factors, including your cancer's stage, your age and overall health, the likelihood that a particular treatment will work and your feelings about it. Your doctor will also consider any treatments you've already had. Options such as immunotherapy and targeted treatments may also be combined to attack the cancer from multiple angles.

Current treatments for advanced kidney cancer include:

- **Immunotherapy.** This treatment boosts the body's immune system to destroy cancer cells.
- **Targeted therapy.** This treatment targets specific gene mutations that enable cancer to grow. (Learn more about immunotherapy and targeted therapy on p. 8)
- **Chemotherapy.** This treatment enters the blood-

ARE YOU A POC?

Black people are currently at the highest risk for kidney cancer, according to the journal *BMC Cancer*, with Hispanic people and Native Americans also at greater risk than White people.

Researchers are still looking into why, and are researching if high blood pressure and/or chronic kidney disease—two conditions also more prevalent in POC—may be a contributing factor in addition to genetics. Because smoking and obesity also increase risk, it can be especially important for POC to shun tobacco and maintain a healthy weight.

If you are experiencing any of the potential symptoms of kidney cancer (see the list, *above*), or you have a family member who has been diagnosed, ask your healthcare provider if a kidney screening might be right for you.



stream and fights cancer cells body-wide. It is not a standard treatment for advanced kidney cancer, and is usually used only if targeted therapy or immunotherapy have failed.

- **Surgery.** Surgery may be used to remove a kidney and surrounding tissue (radical nephrectomy), part of a kidney containing a tumor (partial nephrectomy) or cancer cells that have spread elsewhere (metastectomy). Laparoscopic (using smaller incisions and instruments than those used in open surgery) and robot-assisted laparoscopic approaches (requiring special equipment) may also be used.
- **Thermal ablation.** Ablative treatments may be used when surgery is not recommended. These are typically delivered via probe(s) inserted into the tumor through which either cold (e.g. cryosurgery) or heat energy (e.g. radiofre-

quency) is delivered. With cryosurgery, freeze/thaw cycles are used to destroy the cancer cells, while with radiofrequency ablation, current is used to heat and destroy the tumor.

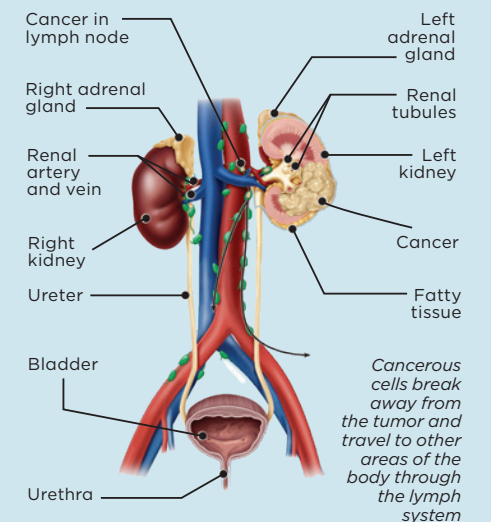
- **Radiation.** High-energy X-rays target and destroy cancer cells; in advanced kidney cancer, this therapy is mainly used in areas where malignant cells have spread.

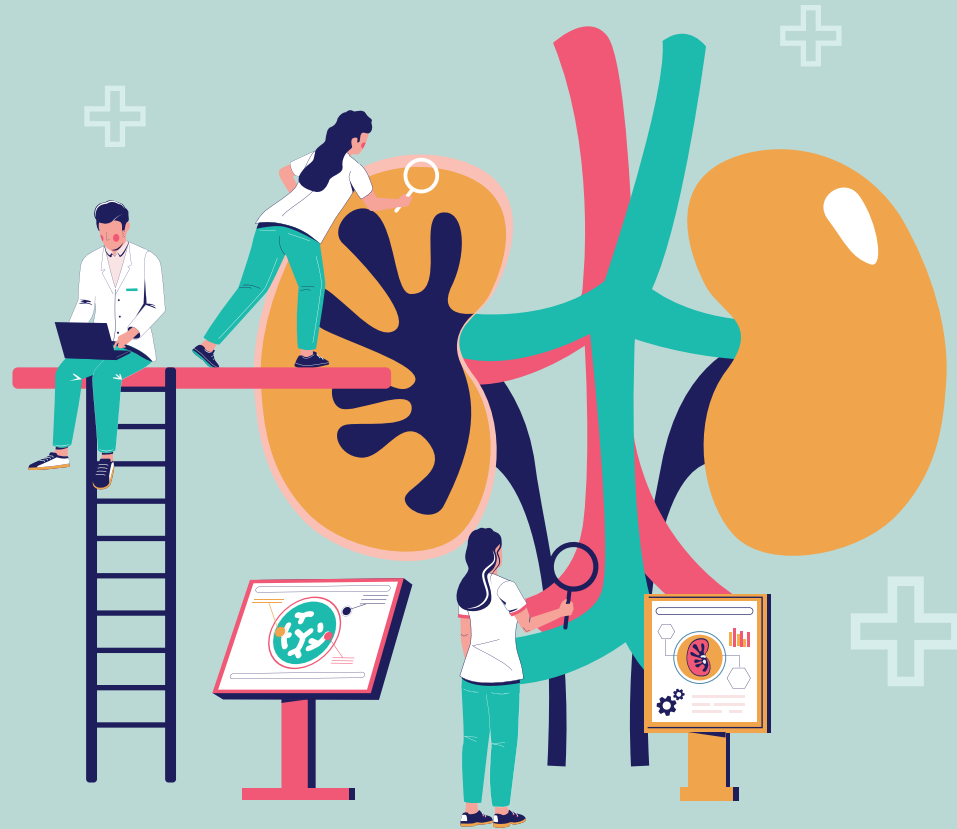
Some people may also consider taking part in a clinical trial, which contributes to cancer research. (Learn more on p. 7.)

The treatment journey is different for every person; but the good news is that today's options are more varied and advanced than ever. By working closely with your cancer care team, chances are that they will find a treatment that works for you. And, like Stanley, you'll probably find that advanced kidney cancer is no reason to put your life on hold! ●

ADVANCED KIDNEY CANCER

In stage III kidney cancer, the cancer has spread to lymph nodes near the kidney, a main kidney blood vessel, or fatty tissue around the kidney. In stage IV kidney cancer, the cancer has spread beyond the fatty tissue around the kidney or to another organ, such as the brain, lungs or bones, or to distant lymph nodes or tissue.





Your advanced kidney cancer healthcare team

These medical professionals can diagnose and help treat advanced kidney cancer.

Nephrologist:

MD who specializes in diseases that impact the kidney, who may have diagnosed your cancer and can provide ongoing care

Nephro-oncologist:

MD who specializes in treating kidney cancer

Urologic oncologist/urologist:

MD who specializes in cancers of the genitourinary tract

Medical oncologist:

MD who specializes in treating cancer using systemic treatments such as chemotherapy, immunotherapy and targeted therapy

Radiation oncologist:

MD who specializes in treating cancer using radiation therapy

Surgical oncologist:

MD who specializes in treating cancer using surgery

Pathologist:

MD who looks at tissue obtained by biopsy or surgery to help diagnose kidney cancer

Palliative care doctor:

MD who specializes in preserving quality of life through pain management and symptom relief

Radiologist:

MD who may perform X-rays, MRI scans, CT scans and nuclear medicine studies

Oncology nurse:

nurse who provides care, support and education during cancer treatment

Infusion nurse:

nurse who administers medications, such as chemotherapy, through infusions and/or injections, and supportive care

Nurse navigator:

nurse who educates and provides resources you may need during treatment

Clinical trials: Are you a candidate?

Astounding progress is being made in the treatment of advanced kidney cancer. By participating in a clinical trial, you may be able to benefit from the latest breakthroughs.

Here's what you can do:

1. Search for trials

Clinical trials are run by many different sponsors—private companies, the U.S. government, hospitals, etc.—so there is no single list that includes them all, but the search tools at the National Cancer Institute's website, *Cancer.gov/clinicaltrials/search*, and at the U.S. National Library of Medicine's site, *ClinicalTrials.gov*, are two of the most comprehensive and reliable.

2. Read the summaries

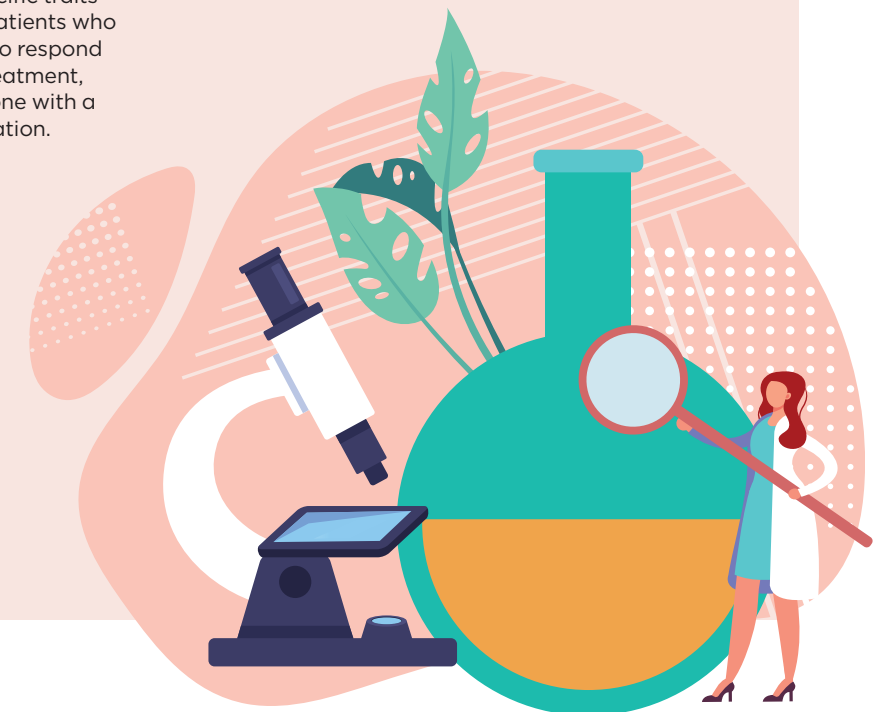
Trial summaries will give you the facts about the study so you can determine if you're a good fit. What to consider:

- Do you meet all the criteria? Clinical trials are often looking for people who fit specific traits—they may only want patients who have tried and failed to respond to a certain type of treatment, for example, or someone with a specific genomic mutation.
- Location of the trial
- Length of the trial
- What is the trial objective?

3. Contact the trials

Ask to speak with the trial coordinator, the referral coordinator or the protocol assistant. It's also possible to have your healthcare provider call for you, as they might be better able to answer any of the trial representative's questions to determine if you're eligible. Some questions you or your healthcare provider should ask:

- What are the risks, benefits and potential side effects?
- Is the trial randomized?
- Could you be given a placebo?
- Who will cover costs (such as travel)?
- Will it affect your everyday life?
- Are similar trials or drugs available through your own oncologist? ●



A closer look at immunotherapy and targeted therapy

Thanks to groundbreaking new treatments, more than 15.5 million people are now cancer survivors. Read on to learn more about two of the newest developments in cancer treatment: immunotherapy and targeted therapy, which are changing prognoses and improving quality of life for many, even those with advanced kidney cancer.

IMMUNOTHERAPY

- **What is it?** Immunotherapy treatments stimulate a person's own immune system to identify and destroy cancer cells.
- **How do immunotherapy medications work?** Immunotherapies "mark" cancer cells so the immune system can more easily find and destroy them. Immunotherapies also give the immune system a boost, so it can better fight cancer cells.
- **How is immunotherapy different from chemotherapy?** Chemotherapy is aimed at all rapidly dividing cells, whether cancerous or not. Immunotherapy is aimed at immune cells, enabling them to attack cancer cells.
- **Can an immunotherapy medication treat advanced kidney cancer?** Yes. Immunotherapies are already approved by the Food and Drug Administration to treat advanced kidney cancer. (Sometimes two immunotherapies are given in combination.) Ask your doctor if you may be eligible.

Immunotherapies—at a glance

THERAPIES	HOW THEY WORK
Monoclonal antibodies	These man-made versions of immune system proteins can be used to target a specific part of a cancer cell. Many monoclonal antibody medications are checkpoint inhibitors. (See below.)
Checkpoint inhibitors	Cancer cells can sometimes manipulate molecules (aka "checkpoints") on immune cells so the immune cells won't recognize and attack them. Checkpoint inhibitors target these molecules, enabling the immune system to recognize and attack the cancer.
Cancer vaccines	Treatment (vs. preventive) vaccines boost your immune system's response to cancer cells.
Cytokines	Cytokines help your immune system fight cancer cells; they may be used alone or in combination with other treatments, such as chemotherapy.
Other immunotherapies	Additional therapies to fight a variety of cancers are available; some are being studied in clinical trials.



TARGETED THERAPY

- **What is it?** Targeted therapy blocks specific molecules that signal cancer cells to multiply and spread. It is used to slow the growth of cancer, kill cancer cells or relieve symptoms caused by cancer. Targeted therapy is primarily used for cancers that overproduce specific proteins or have certain gene and protein mutations.
- **How do targeted therapies work?** Targeted therapies work in different ways depending on if they target a molecule within or on the surface of the cancer cell. Some attach to proteins inside a cancer cell to block the process that tells cells to grow, and some block enzymes that cancer cells use to reproduce.
- **How is targeted therapy different from chemotherapy?** Chemotherapy is aimed at all rapidly dividing cells, whether cancerous or not. Targeted therapy is aimed at specific aspects of cancer cells to stop them from growing and dividing.
- **Can a targeted therapy treat advanced kidney cancer?** Yes. Targeted therapies are already approved by the Food and Drug Administration to treat advanced kidney cancer, and are usually given along with other types of therapies, including immunotherapies. Ask your doctor if you may be eligible.

Targeted therapies—at a glance

THERAPIES	HOW THEY WORK
Angiogenesis inhibitors	These drugs block the cancer's ability to grow new blood vessels that contain nutrients it needs to grow.
Hormone therapies	These drugs either block or stop the production of hormones certain cancers need to grow, such as breast and prostate cancers.
Signal transduction inhibitors	These drugs block signals and enzymes that tell cells to continue to divide and grow.
Gene expression modulators	These drugs change the proteins that control the way gene instructions in cancer cells get carried out.
Apoptosis inducers	These drugs cause cancer cells to go through the natural process of cell death.



COVER STORY

“I’m reclaiming my life!”

Blindsided by a diagnosis of kidney cancer, lifelong fitness enthusiast Brandy Verdin was told she wasn’t a candidate for surgery and should “just accept palliative care.” Refusing to bow down, she turned to her faith and today is giving her cancer a one-two punch with a combination treatment that has her back in the game.

—BY TONYA RUSSELL

CONTINUED ON P. 12

Brandy Verdin's second home is the gym. A 48-year-old retired personal trainer, she's found friends, clients and a sense of purpose among like-minded fitness enthusiasts. The only thing that ranks higher in importance is her family, which has lately grown to include four-month-old granddaughter Sawyer.

But two years ago, her very vitality was on the line as she began having strange health issues. "I went to the doctor for routine bloodwork and found out I had stage II renal failure. The doctor didn't think it was a big deal. In fact, he told me 'not to worry about it.'" So, putting her trust in her doctor, she didn't give it a second thought. But soon after, says Brandy, "My hemoglobin dropped, and I became very sick."

When she started losing weight and becoming severely anemic, she tried tweaking her diet, but that didn't help. Desperate to get to the bottom of her symptoms, she thought about her breast implants: She'd heard they were making some women sick. Could hers be making her sick, too? She decided to have them removed, but when they came out, Brandy explains, "they were intact—no damage or indication they had been causing my health issues." And post-removal, Brandy was still suffering—out of breath and struggling through her sets at the gym. What's more, she began to find blood in her urine.

"I thought I was too healthy to get cancer"

Her doctor referred her to a urologist who suggested the problem might be bladder or kidney cancer, based on Brandy's symptoms.



She was shocked and skeptical: She led a very healthy lifestyle, and cancer didn't run in her family. Yet scans revealed a kidney tumor that was attached to a major vein and had already begun to spread to her lungs. The diagnosis: stage IV renal cell carcinoma.

Instead of feeling devastation or grief, Brandy was confused—and mad. "I felt like my exercise and healthy eating had failed me." But rather than wallow in anger or sadness, she shifted her mindset, opting to view the ordeal as a test of her strong Christian faith and encouraging her husband, Cleveland, and two adult kids, Luke and Brittany, to follow suit.

Even when the surgeon gave her more bad news—"He concluded I wouldn't be a candidate for surgery and that I could only receive palliative care, which would extend my life a little longer"—Brandy turned to prayer and refused to give in. Working with her oncology team, she explored other treatment options, and readily consented when they suggested a combination of immunotherapy (which would help her immune system attack the cancer cells) and targeted therapy (which would block her tumor from growing).

"A combination treatment is making me stronger—and more hopeful"

Although Brandy was mentally prepared to take on the cancer,

physically, she was in bad shape. "I felt beaten. I nearly crawled into the wellness center where I work out to put my contract on hold because I wasn't going to keep paying," she recalls. "But then something held me back—I didn't want to just give up like that, so I changed my mind."

That decision turned out to be the right one, because within weeks of starting the combination therapy, she started to feel a change. "My doctor was amazed at my labs—my blood count doubled quickly, so much so I nearly wasn't considered anemic anymore." With that improvement, her energy levels began to rebound, giving her more stamina to work out—and return to a lifestyle she loved.

Today, halfway through treatment, her cancer is responding well, and her kidney and liver function have improved. Instead of looking into palliative care, Brandy is turning her sights on the weight room again. While she's not quite up to her previous five workouts a week, she goes in for three now and is seeing results.

"When I started lifting again, I was humbled quickly—even air squats were a challenge," says Brandy. "But I'm building my strength back up, I'm progressing, my muscle mass is coming back and I'm so excited! Maybe devoting so much time to fitness didn't prevent me from getting cancer, but that, modern medicine, my faith and my family? Well they're absolutely why I'm still here fighting it." ●

Photos by Scott Myers



Giving cancer treatment your all

Here's how Brandy is staying focused and optimistic.

Eat with your future in mind.

"I plan on living, and I don't want to trash my other organs because I want to eat my feelings," says Brandy. So instead of leaning into bad habits, she sticks with the same wholesome eating program she followed before her diagnosis, shunning processed foods in favor of whole foods rich in nutrients and fiber.

Find an outlet.

"Fitness is my personal stress reliever, and it takes my mind off my diagnosis, but you need to find whatever works for you," Brandy says, adding

that can be anything from spending more time with family, meditating or taking up a new hobby.

Lean on your spirituality.

"God has a hand in my treatment, and I believe He gives scientists the wisdom to create the medicines. People ask if I'm ever skeptical if the medications I'm receiving are helping me, but I'm wise enough to know that God gave me the skills I need to train clients, and he gives doctors and pharmacists the skills they need to treat me—and the scans are proving that true!"



YOU & YOUR CARE TEAM

Keep track of your symptoms

Check the boxes to indicate any symptoms or side effects you're experiencing and how often they are affecting your life, then share this page with your care team so they can help you feel your best:

<u>SYMPTOM</u>	Doesn't affect me	Rarely	A few times a week	Daily	Multiple times a day
Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Stomach cramping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nausea/vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Constipation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Skin rash	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rapid heartbeat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dizziness	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Headache	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Joint pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling down or depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

List the current medications you are taking, including anything over-the-counter or any supplements:

List any conditions (e.g., diabetes, heart disease, etc.) you've been diagnosed with since your last visit:

List any major life events (e.g., job change, divorce, moving) that have occurred since your last visit:



WATER CONSUMPTION My father is undergoing treatment for advanced kidney cancer—should he drink more or less water to help his kidneys function more easily?

Q

A

Answers to your questions about advanced kidney cancer

A: Your father will either undergo (or has undergone) surgery to remove the cancer in his kidney, systemic (body-wide) therapy for kidney cancer metastases, or a combination of these treatments (surgery + systemic therapy). Kidney cancer surgery causes loss of kidney tissue, whether an entire kidney is removed or just the part containing the cancer, which results in diminished kidney function. It is important to stay well-hydrated after such procedures to allow good blood flow to the remaining kidney tissue. It is equally important to adopt a low salt diet (we typically recommend a “no added sodium” diet, as there is quite

a bit of salt in most foods already), and to favor vegetable rather than meat sources of protein, as they are easier for the kidneys to handle. If your father is undergoing systemic therapy rather than renal surgery, hydration can be important as well, as the kidney(s) help clear some of the therapies that may be administered. Hydration also ensures that medications will reach their targets through the bloodstream and is important in case there is therapy-related nausea, vomiting or diarrhea. Finally, good hydration helps prevent blood clots, which are more common in patients with cancer and in patients having surgery of any kind.

TREATMENT WORRIES

Q: My oncologist recommended a combination immunotherapy/targeted therapy to treat my stage III renal cancer. The idea of multiple medications at once scares me—does that mean I'm going to have double the side effects? Am I going to lose my hair like with chemo?

A: The systemic therapies used to treat advanced kidney cancer are not like traditional chemotherapy that destroys all fast-growing cells (such as those in the GI tract and scalp, which is why chemo can cause side effects like nausea, diarrhea and hair loss). Traditional chemotherapy does not work against advanced kidney cancer, but immunotherapy and targeted therapies do. These newer agents *only* attack pathways used by kidney cancer cells to grow and/or help the immune system “see” the cancer and attack it more effectively. It's quite common today for immunotherapies and targeted therapies to be given in combination because it's an effective treatment strategy for many people, and the good news is, even combined, these newer medications usually have much fewer side effects than chemo. ●

OUR EXPERT: Christian Paul Pavlovich, MD, Bernard L. Schwartz Distinguished Professor in Urologic Oncology, Professor of Urology, Johns Hopkins



Facing advanced kidney cancer (RCC)?

KEYTRUDA and LENVIMA are prescription medicines used together to treat a kind of kidney cancer called advanced renal cell carcinoma (RCC) as your first treatment when your kidney cancer has spread or cannot be removed by surgery.

It is not known if LENVIMA is safe and effective in children.



Important Safety Information for KEYTRUDA

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA 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 any time during treatment or even after your treatment has ended.

Call or see your health care provider right away if you develop any signs or symptoms of the following problems or if they get worse. These are not all of the signs and symptoms of immune system problems that can happen with KEYTRUDA:

Lung problems: cough, shortness of breath, or 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; or 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); or bleeding or bruising more easily than normal.

Hormone gland problems: 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: decrease in the amount of your 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 your mouth or in your nose, throat, or genital area; fever or flu-like symptoms; swollen lymph nodes.

Problems can also happen in other organs and tissues. Signs and symptoms of these problems 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.

Important Safety Information for KEYTRUDA continued on next page.



Actor portrayal.

KEYTRUDA + LENVIMA may be your first treatment

Two medicines. One combination that may help you fight advanced kidney cancer (RCC). Your doctor can help you decide if KEYTRUDA + LENVIMA could be right for you.

Ask your doctor if **KEYTRUDA + LENVIMA** is right for you
KeytrudaLenvima.com/AdvancedRCC

Important Safety Information for LENVIMA

LENVIMA may cause serious side effects, including:

High blood pressure (hypertension): High blood pressure is a common side effect of LENVIMA and can be serious. Your blood pressure should be well controlled before you start taking LENVIMA. Your healthcare provider should check your blood pressure regularly during treatment with LENVIMA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure.

Heart problems: LENVIMA can cause serious heart problems that may lead to death. Call your healthcare provider right away if you get symptoms of heart problems, such as shortness of breath or swelling of your ankles.

Problem with blood clots in your blood vessels (arteries): Get emergency medical help right away if you get any of the following symptoms: severe chest pain or pressure; pain in your arms, back, neck, or jaw; shortness of breath; numbness or weakness on one side of your body; trouble talking; sudden severe headache; sudden vision changes.

Liver problems: LENVIMA may cause liver problems that may lead to liver failure and death. Your healthcare provider will check your liver function before and during

treatment with LENVIMA. Tell your healthcare provider right away if you have any of the following symptoms: your skin or the white part of your eyes turns yellow (jaundice); dark "tea-colored" urine; light-colored bowel movements (stools); feeling drowsy, confused or loss of consciousness.

Kidney problems: Kidney failure, which can lead to death, has happened with LENVIMA treatment. Your healthcare provider should do regular blood tests to check your kidneys.

Increased protein in your urine (proteinuria): Proteinuria is a common side effect of LENVIMA and can be serious. Your healthcare provider should check your urine for protein before and during your treatment with LENVIMA.

Diarrhea: Diarrhea is a common side effect of LENVIMA and can be serious. If you get diarrhea, ask your healthcare provider about what medicines you can take to treat your diarrhea. It is important to drink more water when you get diarrhea. Tell your healthcare provider or go to the emergency room, if you are unable to drink enough liquids and your diarrhea is not able to be controlled.

An opening in the wall of your stomach or intestines (perforation) or an abnormal connection (continued)

Important Safety Information for LENVIMA continued on next page.

Important Safety Information for KEYTRUDA (continued)

Infusion reactions that can sometimes be severe or life-threatening. Signs and symptoms of infusion reactions may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feeling like passing out, fever, and back pain.

Rejection of a transplanted organ. Your health care provider should tell you what signs and symptoms you should report and they will monitor you, depending on the type of organ transplant that you have had.

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 KEYTRUDA. Your health care provider will monitor you for these complications.

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

Before you receive KEYTRUDA, tell your health care provider if you have immune system problems such as Crohn's disease, ulcerative colitis, or lupus; have had an organ transplant or have had or plan to have a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic); have had radiation treatment in your chest area; have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.

If you are pregnant or plan to become pregnant, tell your health care provider. KEYTRUDA can harm your unborn baby. If you are able to become pregnant, you will be given a pregnancy test before you start treatment. Use effective birth control during treatment and for 4 months after your last dose of KEYTRUDA. Tell them right away if you think you may be pregnant or you become pregnant during treatment with KEYTRUDA.

Tell your health care provider if you are breastfeeding or plan to breastfeed. It is not known if KEYTRUDA passes into your breast milk. Do not breastfeed during treatment with KEYTRUDA and for 4 months after your last dose of KEYTRUDA.

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

Common side effects of KEYTRUDA when given with LENVIMA include low levels of thyroid hormone; high blood pressure; feeling tired; diarrhea; joint and muscle pain; nausea; decreased appetite; vomiting; mouth sores; weight loss; stomach-area (abdominal) pain; urinary tract infection; protein in your urine; constipation; headache; bleeding; blisters or rash on the palms of your hands and soles of your feet; hoarseness; rash; liver problems; and kidney problems.

These are not all the possible side effects of KEYTRUDA. Talk to your health care provider for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please read the adjacent Important Information about KEYTRUDA and discuss it with your doctor.

Important Safety Information for LENVIMA (continued)

between two or more body parts (fistula): Get emergency medical help right away if you have severe stomach (abdomen) pain.

Changes in the electrical activity of your heart called QT prolongation: QT prolongation can cause irregular heartbeats that can be life threatening. Your healthcare provider will do blood tests before and during your treatment with LENVIMA to check the levels of potassium, magnesium, and calcium in your blood, and may check the electrical activity of your heart with an ECG.

Low levels of blood calcium (hypocalcemia): Your healthcare provider will check your blood calcium levels during treatment with LENVIMA and may tell you to take a calcium supplement if your calcium levels are low.

A condition called Reversible Posterior Leukoencephalopathy Syndrome (RPLS): Call your healthcare provider right away if you get severe headache, seizures, weakness, confusion, or blindness or change in vision.

Bleeding: LENVIMA may cause serious bleeding problems that may lead to death. Tell your healthcare provider if you have any signs or symptoms of bleeding during treatment with LENVIMA, including severe and persistent nose bleeds; vomiting blood; red or black (looks like tar) stools; blood in your urine; coughing up blood or blood clots; heavy or new onset vaginal bleeding.

Change in thyroid hormone levels: Your healthcare provider should check your thyroid hormone levels before starting and every month during treatment with LENVIMA.

Wound healing problems: Wound healing problems have happened in some people who take LENVIMA. Tell your healthcare provider if you plan to have any surgery before or during treatment with LENVIMA.

- You should stop taking LENVIMA at least 1 week before planned surgery.
- Your healthcare provider should tell you when you may start taking LENVIMA again after surgery.

Severe jaw bone problems (osteonecrosis). Severe jaw bone problems have happened in some people who take LENVIMA. Certain risk factors such as taking a bisphosphonate medicine or the medicine denosumab, having dental disease, or an invasive dental procedure may increase your risk of getting jaw bone problems. Your healthcare provider should

examine your mouth before you start and during treatment with LENVIMA. Tell your dentist that you are taking LENVIMA. It is important for you to practice good mouth care during treatment with LENVIMA. Tell your healthcare provider right away if you have any signs or symptoms of jaw bone problems during treatment with LENVIMA, including jaw pain, toothache, or sores on your gums, and if you plan to have any dental procedures before or during treatment with LENVIMA.

- You should stop taking LENVIMA at least 1 week before planned dental surgery or invasive dental procedures.
- Your healthcare provider should tell you when you may start taking LENVIMA again after dental procedures.

The most common side effects of LENVIMA when given with KEYTRUDA include decrease in thyroid hormone levels, increased blood pressure, tiredness, diarrhea, joint and muscle pain, nausea, decreased appetite, vomiting, mouth sores, weight loss, stomach-area (abdominal) pain, urinary tract infection, protein in your urine, constipation, headache, bleeding, rash, redness, itching, or peeling of your skin on your hands and feet, hoarseness, and rash.

LENVIMA may cause fertility problems in males and females and can harm your unborn baby. Tell your healthcare provider if you are:

- pregnant or plan to become pregnant. For females who are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with LENVIMA. Use an effective method of birth control during treatment with LENVIMA and for 30 days after the last dose of LENVIMA
- breastfeeding or plan to breastfeed. It is not known if LENVIMA passes into your breast milk. Do not breastfeed during treatment with LENVIMA and for 1 week after the last dose

Your healthcare provider may need to reduce your dose of LENVIMA, or delay or completely stop treatment if you have certain side effects.

These are not all the possible side effects of LENVIMA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please read the adjacent Important Information about LENVIMA and discuss it with your doctor.



Learn more at KeytrudaLenvima.com/AdvancedRCC



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Important Information About KEYTRUDA® (pembrolizumab) injection 100 mg. Please speak with your healthcare professional regarding KEYTRUDA (pronounced key-true-duh). Only your healthcare professional knows the specifics of your condition and how KEYTRUDA may work with your overall treatment plan. If you have any questions about KEYTRUDA, speak with your healthcare professional. **Rx ONLY**

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

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA 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.

Call or see your healthcare provider right away if you develop 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

- 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

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

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your 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 and symptoms of immune system problems that can happen with KEYTRUDA. 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

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

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

Rejection of a transplanted organ. Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

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 KEYTRUDA. Your healthcare provider will monitor you for these complications.

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

What is KEYTRUDA?

KEYTRUDA is a prescription medicine used to treat:

- a kind of kidney cancer called renal cell carcinoma (RCC).
 - KEYTRUDA may be used with the medicine lenvatinib as your first treatment when your kidney cancer has spread or cannot be removed by surgery (advanced RCC).
- a kind of uterine cancer called advanced endometrial carcinoma.
 - KEYTRUDA may be used with the medicine lenvatinib:
 - when a laboratory test shows that your tumor is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H), **and**
 - you have received anti-cancer treatment, and it is no longer working, **and**
 - your cancer cannot be cured by surgery or radiation.

Before receiving KEYTRUDA, 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 received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. KEYTRUDA can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with KEYTRUDA.
- You should use an effective method of birth control during and for 4 months after the last dose of KEYTRUDA. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you think you may be pregnant or if you become pregnant during treatment with KEYTRUDA.
- are breastfeeding or plan to breastfeed. It is not known if KEYTRUDA passes into your breast milk. Do not breastfeed during treatment with KEYTRUDA and for 4 months after your last dose of KEYTRUDA.

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

How will I receive KEYTRUDA?

- Your healthcare provider will give you KEYTRUDA into your vein through an intravenous (IV) line over 30 minutes.
- In adults, KEYTRUDA is usually given every 3 weeks or 6 weeks depending on the dose of KEYTRUDA that you are receiving.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of KEYTRUDA? KEYTRUDA can cause serious side effects. See “What is the most important information I should know about KEYTRUDA?”

Common side effects of KEYTRUDA when given with lenvatinib include: low levels of thyroid hormone, high blood pressure, feeling tired, diarrhea, joint and muscle pain, nausea, decreased appetite, vomiting, mouth sores, weight loss, stomach-area (abdominal) pain, urinary tract infection, protein in your urine, constipation, headache, bleeding, blisters or rash on the palms of your hands and soles of your feet, hoarseness, rash, liver problems, and kidney problems.

These are not all the possible side effects of KEYTRUDA.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of KEYTRUDA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about KEYTRUDA that is written for health professionals.

Based on Medication Guide usmg-mk3475-iv-2304r055 revised April 2023.

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Continued on next page.

PATIENT INFORMATION for LENVIMA® (lehn-veema) (lenvatinib) 10 mg and 4 mg capsules for oral use

What is LENVIMA?

LENVIMA is a prescription medicine that is used to treat people with certain kinds of cancer.

- LENVIMA is used to treat adults with a type of kidney cancer called advanced renal cell carcinoma (RCC):
 - along with the medicine pembrolizumab as your first treatment when your kidney cancer has spread or cannot be removed by surgery.
- LENVIMA is used along with another medicine called pembrolizumab to treat advanced endometrial carcinoma (EC), a type of uterine cancer:
 - when a laboratory test shows that your tumor is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H), **and**
 - you have received anti-cancer treatment, and it is no longer working, **and**
 - your cancer cannot be cured by surgery or radiation.

It is not known if LENVIMA is safe and effective in children.

Before you take LENVIMA, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure
- have heart problems
- have a history of blood clots in your arteries (type of blood vessel), including stroke, heart attack, or change in vision
- have or have had liver or kidney problems
- have a history of a tear (perforation) in your stomach or intestine, or an abnormal connection between two or more body parts (fistula)
- have headaches, seizures, or vision problems
- have any bleeding problems
- plan to have surgery, a dental procedure, or have had a recent surgery. You should stop taking LENVIMA at least 1 week before planned surgery. See “**What are the possible side effects of LENVIMA?**”
- are pregnant or plan to become pregnant. LENVIMA can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with LENVIMA.
- You should use an effective method of birth control during treatment with LENVIMA and for 30 days after the last dose of LENVIMA. Talk with your healthcare provider about birth control methods you can use during this time. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with LENVIMA.

- are breastfeeding or plan to breastfeed. It is not known if LENVIMA passes into your breast milk. Do not breastfeed during treatment with LENVIMA and for 1 week after the last dose.

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

Especially tell your healthcare provider if you are taking, or have taken, an osteoporosis medicine.

Know the medicines you take. Keep a list of your medicines to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take LENVIMA?

- Take LENVIMA exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much LENVIMA to take and when to take it. Your healthcare provider may change your dose during treatment, stop treatment for some time, or completely stop treatment with LENVIMA if you have side effects.
- Take LENVIMA 1 time each day at the same time, with or without food.
- If you miss a dose of LENVIMA, take it as soon as you remember. If your next dose is due within 12 hours, skip the missed dose and take the next dose at your regular time.
- Swallow LENVIMA capsules whole. Do not crush or chew the LENVIMA capsules.
- If you cannot swallow LENVIMA capsules whole, LENVIMA capsules can be mixed with water or apple juice, then taken by mouth, or mixed with water and given through a feeding tube.

How to take LENVIMA by mouth if you cannot swallow whole capsules:

- Place your daily dose, up to 5 capsules, in a small container or oral syringe (approximately 20 mL capacity).
- Add 3 mL of **water or apple juice** to the container or oral syringe. **Wait 10 minutes** for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. Do not break or crush the capsules.
- Drink the liquid mixture or use an oral syringe to take directly into the mouth.
- Next, using a second syringe, add an additional 2 mL of liquid to the container or oral syringe (cap the first oral syringe before adding the additional water) then swirl or shake and take the liquid mixture. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the container or oral syringe to make sure all of the medicine is taken.

- If 6 capsules are required for your daily dose, follow the above instructions using 3 capsules at a time.

How to give LENVIMA through a feeding tube:

- LENVIMA should be given in feeding tubes of at least 5 French diameter (polyvinyl chloride or polyurethane tube) and at least 6 French diameter (silicone tube).
 - Place your daily dose, up to 5 capsules, in a syringe (20 mL capacity).
 - Add 3 mL of **water** to the syringe. **Wait 10 minutes** for the capsule shell (outer surface) to dissolve completely, then stir or shake the mixture for 3 minutes until capsules are fully dissolved. Do not break or crush the capsules.
 - Give the mixture through a feeding tube.
 - Next, cap the syringe and remove the plunger. Use a second syringe and add an additional 2 mL of liquid to the syringe. Swirl or shake and give the mixture in the feeding tube. Repeat this step at least one time and until you cannot see any of the LENVIMA mixture left in the syringe to make sure all of the medicine is taken.
 - If 6 capsules are required for your daily dose, follow the above instructions using 3 capsules at a time.
- LENVIMA mixture may be stored in a covered container in the refrigerator at 36°F to 46°F (2°C to 8°C) for a maximum of 24 hours. Throw away the LENVIMA mixture if not used within 24 hours of mixing.
- If you take too much LENVIMA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of LENVIMA?

LENVIMA may cause serious side effects, including:

- **High blood pressure (hypertension).** High blood pressure is a common side effect of LENVIMA and can be serious. Your blood pressure should be well controlled before you start taking LENVIMA. Your healthcare provider should check your blood pressure regularly during treatment with LENVIMA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure.
- **Heart problems.** LENVIMA can cause serious heart problems that may lead to death. Call your healthcare provider right away if you get symptoms of heart problems, such as shortness of breath or swelling of your ankles.
- **Problem with blood clots in your blood vessels (arteries).** Get emergency medical help right away if you get any of the following symptoms:
 - severe chest pain or pressure
 - pain in your arms, back, neck or jaw
 - shortness of breath
 - numbness or weakness on one side of your body
 - trouble talking
 - sudden severe headache
 - sudden vision changes

- **Liver problems.** LENVIMA may cause liver problems that may lead to liver failure and death. Your healthcare provider will check your liver function before and during treatment with LENVIMA. Tell your healthcare provider right away if you have any of the following symptoms:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark “tea colored” urine
- light-colored bowel movements (stools)
- feeling drowsy, confused or loss of consciousness

- **Kidney problems.** Kidney failure, which can lead to death, has happened with LENVIMA treatment. Your healthcare provider should do regular blood tests to check your kidneys.

- **Increased protein in your urine (proteinuria).** Proteinuria is a common side effect of LENVIMA and can be serious. Your healthcare provider should check your urine for protein before and during your treatment with LENVIMA.

- **Diarrhea.** Diarrhea is a common side effect of LENVIMA and can be serious. If you get diarrhea, ask your healthcare provider about what medicines you can take to treat your diarrhea. It is important to drink more water when you get diarrhea. Tell your healthcare provider or go to the emergency room if you are unable to drink enough liquids and your diarrhea is not able to be controlled.

- **An opening in the wall of your stomach or intestines (perforation) or an abnormal connection between two or more body parts (fistula).** Get emergency medical help right away if you have severe stomach (abdomen) pain.

- **Changes in the electrical activity of your heart called QT prolongation.** QT prolongation can cause irregular heartbeats that can be life threatening. Your healthcare provider will do blood tests before and during your treatment with LENVIMA to check the levels of potassium, magnesium, and calcium in your blood, and may check the electrical activity of your heart with an ECG.

- **Low levels of blood calcium (hypocalcemia).** Your healthcare provider will check your blood calcium levels during treatment with LENVIMA and may tell you to take a calcium supplement if your calcium levels are low.

- **A condition called Reversible Posterior Leukoencephalopathy Syndrome (RPLS).** Call your healthcare provider right away if you get severe headache, seizures, weakness, confusion, or blindness or change in vision.

- **Bleeding.** LENVIMA may cause serious bleeding problems that may lead to death. Tell your healthcare provider if you have any signs or symptoms of bleeding during treatment with LENVIMA, including:

- severe and persistent nose bleeds
- vomiting blood
- red or black (looks like tar) stools
- blood in your urine
- coughing up blood or blood clots
- heavy or new onset vaginal bleeding

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- **Change in thyroid hormone levels.** Your healthcare provider should check your thyroid hormone levels before starting and every month during treatment with LENVIMA.
- **Wound healing problems.** Wound healing problems have happened in some people who take LENVIMA. Tell your healthcare provider if you plan to have any surgery before or during treatment with LENVIMA.
 - You should stop taking LENVIMA at least 1 week before planned surgery.
 - Your healthcare provider should tell you when you may start taking LENVIMA again after surgery.
- **Severe jawbone problems (osteonecrosis).** Severe jawbone problems have happened in some people who take LENVIMA. Certain risk factors such as taking a bisphosphonate medicine or the medicine denosumab, having dental disease, or an invasive dental procedure may increase your risk of getting jawbone problems. Your healthcare provider should examine your mouth before you start and during treatment with LENVIMA. Tell your dentist that you are taking LENVIMA. It is important for you to practice good mouth care during treatment with LENVIMA. Tell your healthcare provider right away if you get signs or symptoms of jawbone problems during treatment with LENVIMA, including jaw pain, toothache, or sores on your gums. Tell your healthcare provider if you plan to have any dental procedures before or during treatment with LENVIMA. You should avoid having invasive dental procedures if possible, during treatment with LENVIMA. Stopping your bisphosphonate medicine before an invasive dental procedure may help decrease your risk of getting these jaw problems.
 - You should stop taking LENVIMA at least 1 week before planned dental surgery or invasive dental procedures.
 - Your healthcare provider should tell you when you may start taking LENVIMA again after dental procedures.

The most common side effects of LENVIMA when given with pembrolizumab include:

- decrease in thyroid hormone levels
- increased blood pressure
- tiredness
- diarrhea
- joint and muscle pain
- nausea
- decreased appetite
- vomiting
- mouth sores
- weight loss
- stomach-area (abdomen) pain
- urinary tract infection
- protein in your urine
- constipation
- headache
- bleeding
- rash, redness, itching, or peeling of your skin on your hands and feet
- hoarseness
- rash

LENVIMA may cause fertility problems in males and females. Talk to your healthcare provider if this is a concern for you.

Your healthcare provider may need to reduce your dose of LENVIMA, or delay or completely stop treatment, if you have certain side effects.

These are not all the possible side effects of LENVIMA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LENVIMA?

- Store LENVIMA at room temperature, between 68°F to 77°F (20°C to 25°C).
- **Keep LENVIMA and all medicines out of the reach of children.**

General information about the safe and effective use of LENVIMA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LENVIMA for a condition for which it was not prescribed. Do not give LENVIMA to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about LENVIMA that is written for health professionals.

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“Kidney cancer CAN’T SLOW US DOWN!”



Tracy and Michael know that living with advanced kidney cancer can be tough sometimes—but it doesn’t have to limit your life! Read on for their tips on managing everyday tasks, stress, mental health, fatigue and more.

—BY LINDSAY BOSSLETT

“Tap your newfound strength—and seek joy!”

TRACY “TRA” POYNEER, 50
ANNE ARUNDEL COUNTY, MD

Stay positive.

In early 2020, Tracy “Tra” Poyneer came down with pneumonia. While in the hospital, she discovered two things: She had COVID, and she had stage III kidney cancer. “It was devastating,” recalls the retired real estate marketing exec. “There I am in quarantine, alone, coping with what—at the time—was a frightening new illness, and then they discover my d-Dimer [a test that looks for blood clotting issues] results are too high, so they sent me for a CT scan to check for clots and discovered I had a 9-cm mass on my kidney.” Tra, who refers to her primary tumor as “Karen,” was determined to look on the bright side. “I’m very thankful for my ER doctor, Dr. Todd Rosen of the University of Maryland. He took a chance when he sent me for that CT scan, because ERs had stopped routinely scanning COVID patients for clots at that time. If not for that, we wouldn’t have caught ‘Karen’ when we did.”

Seek a second opinion.

“I was diagnosed with stage III chromophobe (a.k.a. non-clear cell) renal cell carcinoma at the University of Maryland Tate Cancer Center, but I decided to switch to the Lombardi Cancer Center in Georgetown, MD, because they have oncologists who specialize in kidney cancer, and non-clear cell is more rare. There, I was able to have genetic testing done that revealed a defect in my SDHB

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gene. More testing is being done today to see if that defect is linked to my RCC, which could impact treatments in the future. It's important to feel like you and your cancer care team know all they can about your condition—there is always something to learn, especially when genetics plays a role.”

Focus on the “now.”

“To cope with everything, I've been working on honing my fishing, crabbing and boating skills,” says Tra, who lives off Maryland's Magothy River. “Being on the water provides me tranquility, and I learned that healing from cancer *can* mean finding new strength and joy. It changed the way I've viewed life's unexpected challenges and helped me let go of all the negativity I had been carrying.”

Join a support group—or all of them!

“I think I reached out to every support group available,” Tra laughs. “But they were helpful in so many ways, including getting me involved in the kidney cancer community. I'm proud to say I was part of a six-woman team that raised \$50,000 for the first-ever patient-led research grant for my type of RCC through the Kidney Cancer Research Alliance [kccure.org]. Today I feel honored to be able to connect with other rare RCC patients to help them along their jour-

ney and keep advocating for funding for non-clear cell research.”

Avoid the “Google trap.”

“Researching your cancer online will only generate worse-case scenarios. Reach out to oncology specialists who are knowledgeable and who treat others with your RCC subtype. RCC social media support groups can be helpful in this regard, too. You'll find others that have gone through a similar situation or can point you in the right direction.”

Rely on others.

“Having a reliable caregiver, support system and partner was (and is) critical in my journey,” Tra says. “It's hard enough processing a new diagnosis, and the overwhelming amount of anxiety over upcoming scans, without going it

alone. My community rallied around me by providing meals during surgeries, and sending me cards, care packages and uplifting words.”

Find a hero.

“My diagnosis has brought me closer to my husband and even extended family members. I've also learned that I can push myself in ways I never thought possible, both mentally and physically. My parents live on the Eastern Shore in Cambridge, MD, which is Harriet Tubman's birthplace and I've had the privilege of visiting there often. Her story, her strength, her determination, her beauty, her courage and faith have inspired me to keep pushing. She was a remarkable woman and taught me to *#HoldSteady* when you think you can't go on anymore.”



“One positive to my diagnosis is it's brought me closer to the people in my life,” says Tra with husband A.F. and their dog, Latke.

Photo by O'Doherty Photo

Photo by Christopher Analista

“Stay strong—and stay hopeful!”

MICHAEL WHITLEY, 45
HUNTSVILLE, AL

Listen to your body.

Everything changed for Michael Whitley on September 3, 2019. “That's the day my friend, a nephrologist, officially diagnosed my kidney cancer. I've been on treatment, including both immunotherapy and targeted therapy, ever since.” Michael dismissed his initial symptoms, which began in January of that year, as kidney stones, passing “several,” which turned out to be blood clots. “Finally, in September I agreed to go to my friend's clinic for bloodwork and urinalysis. Both came back normal. She pushed me to get a CT scan, and I got a copy of my images when I left the scan center. I texted her an image because I thought my left kidney was ‘inflamed.’ Turns out it was a massive tumor—I'm definitely glad I finally listened to her about getting that scan!” Subsequent tests determined Michael had stage IV clear cell renal cell carcinoma.

Seek a coping mechanism.

“My vision completely narrowed, and I became hyper focused when I was diagnosed. My goal became to learn as much as possible about this cancer and be the best patient possible. So for the first three months, I processed my emotions by doing intense research, looking up journal articles and watching and reading ev-

erything I could about kidney cancer. I didn't fully ‘feel’ the impact of the diagnosis until around December 2019. Then I worked to process my emotions by talking about them with friends and family and making plans for the future regarding my treatment. Having a plan has always made me feel more secure!”

Find your new “normal.”

“When I was diagnosed, I was halfway through an MBA and running my engineering firm, EngeniusMicro. I was completely transparent with my employees and customers. Luckily, I still finished my MBA and was able to keep working while in treatment. I could not have done any of this without my business partners and employees helping to shoulder the load when things were tough.”

Reach out.

“I find support through online forums such as SmartPatients [smartpatients.com] and connections I have made with other kidney cancer patients, advocates and researchers. Working on ‘doing’ rather than just ‘talking’ makes me feel more in control of my disease, so I've recently become active in a patient advocate role, helping to advise newly diagnosed patients, perform research reviews for funding organizations and

advocate for additional research funding for kidney cancer through organizations like the Kidney Cancer Association [kidneycancer.org].”

Find a doctor you trust.

“I sought a second opinion from a kidney cancer expert after my initial diagnosis. Having confidence in my care team is critically important to reducing anxiety about my future treatments. There is so much uncertainty with cancer treatments and it is important to have trust that the team you have assembled is providing you the best advice possible.” ●

Health Monitor

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Find the EMOTIONAL CARE you need

Cancer doesn't only have a bodily impact; it can also cause mental distress. Studies show that anxiety and depression can interfere with a person's adherence to treatment. If you're down, on edge, irritable, or out of sorts, read on to find the right support! —BY MARISSA PURDY



IN-PERSON THERAPY

What it is: A psychologist, psychiatrist, licensed therapist or social worker can work with you to develop a personalized plan specific to your needs using methods such as psychoanalysis, cognitive behavioral therapy, holistic therapy and more.

It might work best for you if: You're not comfortable speaking up in a crowd, you prefer more personalized attention or you're also looking to work through emotional issues not related to your cancer.

How to get started: You can find a licensed practitioner that works for you on [psychologytoday.com](https://www.psychologytoday.com) or [goodtherapy.org](https://www.goodtherapy.org).

TELEHEALTH COUNSELING

What it is: The same type of one-on-one session as in-person therapy but conducted online or via phone or text.

It might work best for you if: You live in a remote area, lack transportation or have mobility issues.

How to get started: Visit Teladoc, an online search engine that can help you get matched with a therapist that fits your lifestyle, or ZocDoc, a platform you can use to find a variety of online healthcare specialists.

SUPPORT GROUPS

What they are: These meetups can sometimes involve people only with your type of cancer, cancer in general or people dealing with any type of chronic health condition. They often gather at hospitals, wellness centers, community centers or churches and are sometimes run by trained professionals.

They might work best for you if: You're looking for information or affirmation from others going through a similar situation as you.

How to get started: Look for flyers at your local hospital, cancer care center or community center, or try searching on [meetup.com](https://www.meetup.com) to find meetings near you.

SOCIAL MEDIA GROUPS

What they are: Online peer support groups where you can connect with people virtually.

They might work best for you if: You're seeking the same type of support as a support group but want to be able to reach out to anyone at any time. These can also be helpful for those who live in remote areas or who otherwise might have difficulty getting to a meeting.

How to get started: Search for "kidney cancer support" or #kidneycancer on social media sites like Facebook, Instagram and Twitter. ●

Need help paying for mental health care?

TRY THESE RESOURCES:

- Cancer Financial Assistance Coalition [cancerfac.org](https://www.cancerfac.org)
- National Patient Advocate Foundation [npaf.org](https://www.npaf.org)



Regular cancer screening can help keep people together.

Call the American Cancer Society at **1-800-227-2345** or visit [cancer.org](https://www.cancer.org).

5 EASY WAYS to lower your recurrence risk!

Recurrence anxiety—the fear of cancer coming back—impacts nearly 70% of cancer patients, with close to 40% reporting depression as a result, according to a study in the journal *Neuropsychiatric Disease and Treatment*. One of the most effective methods for managing those emotions? Gaining back a sense of control. Read on for the common risk factors you can take charge of to lower your risk of recurrence, and see if they could work for you!

—BY MARISSA PURDY



1. KICK THE BUTTS

Smoking is not just a risk factor for lung cancer—it raises your risk for *any* form of cancer recurrence, according to the American Cancer Society (ACS). That's because smoking exposes you to cancer-causing chemicals, including PAH, N-nitrosamines, aromatic amines, 1,3-butadiene, benzene, aldehydes and ethylene oxide, which are absorbed directly into the bloodstream and circulated throughout the body. Today, there are many effective methods to help you cut the habit for good, including medications, addiction counseling and more. Visit smokefree.gov for some tips to help get you started.



2. STAY ACTIVE

You probably already know the American Heart Association recommends 150 minutes a week of physical activity to keep your ticker in top shape, but this recommendation extends to cancer patients in remission, as well. A study by the *Journal of Cancer Survivorship* found that cancer patients in recovery who maintained regular physical activity had a profoundly improved outcome—getting moving not only lowered rates of recurrence and increased survival rates, it also lowered anxiety and depression. The moral? Staying active can significantly improve your mood *and* help stop cancer from returning. And luckily that doesn't mean training for a marathon—study subjects saw improvements using a range of activities, including walking, dancing, yoga and strength-building exercises.



3. LIMIT ALCOHOL INTAKE

Much like smoking impacts more than the lungs, drinking excess alcohol can increase health risks to more than just your liver. In fact, the World Health Organization estimates that anywhere from 4% up to 25% of cancers worldwide are attributable to alcohol. That's because the alcohol we drink—whether beer, wine or liquor—is comprised of ethanol, which can damage our DNA, causing cancer cells to develop. Alcohol also increases risk in other ways, including preventing the absorption of certain antioxidants, and increasing estrogen levels, which can promote the growth of certain estrogen-receptor positive cancers. Luckily, lowering your alcohol-related risk typically does not mean giving up happy hour completely—just keep the amounts you drink within the recommended levels. The Centers for Disease Control and Prevention recommend two drinks or less in a day for men or one drink or less in a day for women, but ask your cancer care team what levels are safe for you.



4. TASTE THE RAINBOW

By upping your intake of colorful fresh fruits and veggies, that is. In general, the same eating plan recommended for a healthy heart and lifestyle applies to lowering your cancer risk, as well. Several studies have linked high consumption of red meat, cured meats, sugar, canned goods (which can contain the carcinogen BPA), fried foods and high-fat dairy to increased risk of dozens of types of cancer. After completing treatment, the ACS recommends filling your plate with whole fruits and vegetables, lean protein (such as chicken and fish), beans, nuts and whole-grain carbs like brown rice.



5. DON'T MISS FOLLOW-UP SCANS

More so than anything else, adhering to your care team's recommended screening schedule can help you detect any signs or symptoms of recurrence before they progress. The Centers for Disease Control and Prevention (CDC) suggest a great way to stay on top of your care is to create a "survivorship care plan" with your team, which includes a record of your treatment history, a schedule for exams and future testing, and different ways they recommend specifically for you to stay healthy. And if a recurrence does occur? Take heart—with today's treatment options, you have every reason to believe you can beat this episode of cancer, as well, and get back to living in remission! ●

How often should I go for follow-up screenings?

Exact recommendations can vary from patient to patient, but generally speaking most patients with advanced stage cancer who achieve a full response from treatment will need scans every 3 to 6 months for the first 3-5 years after treatment and every 6 months to every year going forward.

Health Monitor Living



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Questions to ask at today's exam

What are the results of my latest tests and scans, and what do they indicate about my current treatment?



What should I know about immunotherapy or targeted therapy? Are either or both an option for me?



Is there a clinical trial that can help me? What are the pros and cons of participating in a trial?



Are there any side effects that I should report to you immediately?



If this treatment doesn't work, what are my next options?



What future tests will I need to track my progress?



What are the side effects I can expect?



Can I still work while undergoing treatment?



Do you know of any support groups I can join?



On treatment and need help covering the cost?

Ask your healthcare provider about patient assistance programs or call the manufacturer of the treatment you have been prescribed. Many pharmaceutical companies offer copay assistance programs that can make treatment more affordable.