UNDERSTANDING
BLADDER CANCER
A Treatment Guide for Patients and their Families

Where information equals hope
**Setting Our Sights On Living Longer**

PADCEV™ was studied in adults with advanced bladder cancer who had previously received an immunotherapy and platinum-containing chemotherapy. In the study, median overall survival with PADCEV was 13 months versus 9 months with chemotherapy.

Please see Important Safety Information below and talk to your doctor about side effects.

**IMPORTANT SAFETY INFORMATION**

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

PADCEV may cause serious side effects, including:

- **Skin Reactions.** Severe skin reactions have happened in people treated with PADCEV; in some cases severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle (28 days) of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:
  - target lesions (skin reactions that look like rings)
  - rash or itching that continues to get worse
  - blistering or peeling of the skin
  - painful sores or ulcers in mouth or nose, throat, or genital area
  - fever or flu-like symptoms
  - swollen lymph nodes

See “What are the possible side effects of PADCEV?” for more information about side effects.

**WHAT IS PADCEV?**

PADCEV is a prescription medicine used to treat adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery. PADCEV may be used if you:

- have received an immunotherapy medicine and chemotherapy that contains platinum, or
- you are not able to receive a chemotherapy that contains the medicine cisplatin and you have received one or more prior therapy.

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

**Before receiving PADCEV, tell your healthcare provider about all of your medical conditions, including if you:**

- are currently experiencing numbness or tingling in your hands or feet
- have a history of high blood sugar or diabetes
- have liver problems
- are pregnant or plan to become pregnant. PADCEV can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with PADCEV
- are breastfeeding or plan to breastfeed. It is not known if PADCEV passes into your breast milk. Do not breastfeed during treatment and for at least 3 weeks after the last dose of PADCEV
- are planning to become a father. PADCEV may cause severe side effects that could affect the ability to father children. Talk to your healthcare provider about these effects before you start treatment with PADCEV.

**Females who are able to become pregnant:**

- Your healthcare provider should do a pregnancy test before you start treatment with PADCEV.
- You should use an effective method of birth control during your treatment and for at least 2 months after the last dose of PADCEV.

**Males with a female sexual partner who is able to become pregnant:**

- If your female partner is pregnant, PADCEV can harm the unborn baby.
- You should use an effective method of birth control during your treatment and for at least 4 months after the last dose of PADCEV.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PADCEV with certain other medicines may cause side effects.

**How will I receive PADCEV?**

- PADCEV will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- You will receive your PADCEV over periods of time called cycles.
  - Each PADCEV cycle is 28 days.
  - You will receive PADCEV on days 1, 8 and 15 of every cycle.
- Your healthcare provider will decide how many treatment cycles you need.
- Your healthcare provider may do blood tests regularly during treatment with PADCEV.

**What are the possible side effects of PADCEV?**

PADCEV may cause serious side effects, including:

- **Skin Reactions.** See “Skin Reactions” above for more information.
PADCEV is approved to treat your advanced bladder cancer* if you have received:

**Immunotherapy and platinum-containing chemotherapy** OR **Prior therapy and could not receive cisplatin chemotherapy**

Ask your healthcare professional if PADCEV is right for you or your loved one

Scan the QR code to visit PADCEV.com for more information

*Bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra) that has spread or cannot be removed by surgery.

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**The most common side effects of PADCEV include:**
- skin rash
- changes in liver and kidney function tests
- increased sugar (glucose) in the blood
- tiredness
- numbness or tingling in your hands or feet, or muscle weakness
- decreased white blood cell, red blood cell, and platelet counts
- hair loss
- decreased appetite

If you have certain side effects, your healthcare provider may decrease your dose or stop your treatment with PADCEV for a period of time (temporarily) or completely.

PADCEV may cause fertility problems in males, which may affect the ability to father children. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of PADCEV.

Please see Brief Summary of full Prescribing Information (Prescription Drug Facts), with an Important Warning of Serious Side Effects on adjacent page.
**Prescription Drug Facts**

**Active Ingredient**  
PADCEV (enfortumab vedotin-eũfv) injection for IV infusion 20mg or 30mg vials

**Rx Only**  
Purpose

**Important Warning**  
Severe skin reactions have happened in people treated with PADCEV, in some cases severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle (28 days) of treatment but may happen later. Your healthcare provider will monitor you, may stop your treatment with PADCEV completely or for a period of time (temporarily), may change your dose, and may prescribe medicines if you get skin reactions. Tell your healthcare provider right away if you develop any of these signs of a new or worsening skin reaction:
- Target lesions (skin reactions that look like rings)
- Rash or itching that continues to get worse
- Blistering or peeling of the skin
- Painful sores or ulcers in mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

See “Warnings” below for more information about serious side effects of PADCEV.

**Uses**  
Treatment of adults with bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra) that has spread or cannot be removed by surgery. PADCEV may be used if you:

- Have received an immunotherapy medicine and chemotherapy that contains platinum, or
- You are not able to receive a chemotherapy that contains the medicine cisplatin and you have received one or more prior therapy.

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

**Warnings**  
Ask a doctor before use if you have
- Numbness or tingling in your hands/feet
- Have a history of high blood sugar or diabetes
- Have liver problems

What are the possible serious side effects of PADCEV?
- Skin reactions. See “Important Warning” above
- High blood sugar (hyperglycemia), including diabetic ketoacidosis (DKA), sometimes resulting in death
- Lung problems
- Nerve problems (peripheral neuropathy) like tingling in your hands or feet or muscle weakness
- Eye problems
- Infusion site reactions if PADCEV leaks out of your veins into tissues around your infusion site (extravasation)

Tell your doctor if you have
- Target lesions (skin reactions that look like rings), rash/itching that continues to get worse, skin blistering or peeling, painful sores in the mouth, nose, throat, or genital area, fever/flu-like symptoms, or swollen lymph nodes
- Frequent urination, increased thirst, blurred vision, confusion, it becomes harder to control your blood sugar, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting, or stomach pain
- Trouble breathing, shortness of breath, or cough
- Numbness or tingling in your hands or feet or muscle weakness
- Dry eyes, blurred vision, or any vision changes
- Redness, swelling, itching, or discomfort at the infusion site, or get medical help right away.

If pregnant, able to become pregnant, or have a partner who is able to become pregnant
- PADCEV can harm your unborn baby, talk to your doctor
- Females should use effective birth control during treatment and for at least 2 months after the last dose of PADCEV
- Males should use effective birth control during treatment and for at least 4 months after the last dose of PADCEV

If breastfeeding
- Do not breastfeed during treatment and for at least 3 weeks after the last dose of PADCEV

Fertility
- PADCEV may cause fertility problems in males, which may affect the ability to father children
**Prescription Drug Facts Continued**

### Most Common Side Effects
- Skin rash
- Changes in liver and kidney function tests
- Increased sugar (glucose) in the blood
- Tiredness
- Numbness or tingling in your hands or feet, or muscle weakness
- Decreased white blood cell, red blood cell, and platelet counts
- Hair loss
- Decreased appetite
- Diarrhea
- Decreased sodium, phosphate, and protein (albumin) in the blood
- Nausea
- Itching
- Change in sense of taste
- Increased uric acid in the blood
- Increased lipase (a blood test done to check your pancreas)
- Decreased weight
- Dry skin

If you have certain side effects, your healthcare provider may decrease your dose or stop your treatment with PADCEV for a period of time (temporarily) or completely.

These are not all of the possible side effects of PADCEV. You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### Directions
- PADCEV will be given by intravenous (IV) infusion over 30 minutes.
- You will receive PADCEV over periods of time called cycles.
- Each cycle is 28 days and PADCEV will be given on days 1, 8, and 15 of every cycle.
- Your doctor will decide how many treatment cycles you need.
- Your doctor may do blood tests regularly during your treatment.

### Other Information
Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking PADCEV with certain other medicines may cause side effects.

If you would like more information about PADCEV, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about PADCEV that is written for healthcare professionals (full Prescribing Information) which includes more information about the Important Warning with PADCEV.

### Inactive Ingredients
Histidine, histidine hydrochloride monohydrate, polysorbate 20, and trehalose dehydrate.
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“Facing cancer is scary, but I tell others not to ever give up. I live by my motto ‘Improvise, adapt and overcome.’”

— Ron Speidel, page 7

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PRP PATIENT RESOURCE PUBLISHING®
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Understanding a bladder cancer diagnosis

Partnering with your doctor and using trusted resources will be important to learning as much as you can about the type of bladder cancer you have so you can make informed treatment decisions. Seek out a doctor or cancer center that uses a multidisciplinary team to assist you along the way. In addition, it can be helpful to learn from other bladder cancer survivors who may share valuable advice and information.

About the bladder
As part of the urinary tract, the bladder helps eliminate waste from the body. The urinary tract, which includes the renal pelvis, ureters, bladder, and urethra, is lined with urothelial cells that can change shape and stretch without breaking apart. This is particularly important for the functioning of the bladder, which expands and contracts as urine collects in or is expelled from the bladder.

The bladder is a hollow expandable muscular organ that collects and stores urine produced in the kidneys (see The Urinary Tract, page 6). Urine flows from the kidneys to the bladder through two thin tubes called ureters. The bladder wall is flexible, and the bladder can hold approximately two cups of urine. When it is full and you are ready to urinate, the muscles in the bladder wall contract and force the urine out of the body through a tube called the urethra.

The bladder wall is composed of four layers:
- Urothelium: Also called the transitional epithelium or mucosa, this innermost layer is composed of cells called urothelial or transitional cells.
- Lamina propria: The next layer is composed of thin connective tissue, blood vessels and nerves.
- Muscularis propria: The third layer is made up of thick muscle. Together with the lamina propria, it is also called the submucosa.
- Perivesical fat: The outermost layer, also called the serosa, is made up of fatty connective tissue to help separate the bladder from nearby organs and protect it.

How bladder cancer begins
Bladder cancer develops when gene(s) in normal cells mutate and multiply uncontrollably. They form a disorganized mass of billions of abnormal cells called a tumor.

The most common type of bladder cancer is urothelial carcinoma, also called transitional cell carcinoma. Other forms (called histologic subtypes) of bladder cancer include squamous cell carcinoma, adenocarcinoma and small cell carcinoma, all of which are almost always invasive. Distinguishing one histologic type of cancer from another is based on the appearance of the cells under a microscope.

Continued on page 6
Also important in describing bladder cancer is its form, or morphology. There are two subtypes: papillary and flat. Papillary tumors grow from the bladder’s inner lining and project toward the center of the bladder while flat tumors grow along the surface of the lining.

Bladder tumors are also described by their invasiveness:
- Non-invasive tumors have not penetrated any other layers of the bladder.
- Non-muscle invasive tumors have grown into the lamina propria but not into the muscle.
- Muscle-invasive tumors have grown into the bladder wall’s muscle and sometimes into surrounding tissues or organs outside the bladder, such as the liver, lung or bone.

UNDERSTANDING STAGING AND GRADING
Bladder cancer is classified according to the tumor, node and metastasis (TNM) system developed by the American Joint Committee on Cancer (AJCC). Doctors categorize the tumor (T) according to its depth of invasion, whether cancer cells are found in nearby lymph nodes (N), and whether it has metastasized (M), or spread, to other parts of the body. Once the cancer is classified, an overall stage is assigned (see Tables 1 and 2).

Bladder tumors are given a clinical stage based on the results of a physical examination, evaluation of biopsy specimens and the results of imaging studies and CT scans. A pathologic stage is then based on more invasive testing, including surgery, to accurately establish how far the disease has spread (see Illustrated Stages of Bladder Cancer, page 5). If cancer spreads beyond the bladder, your doctor may recommend biomarker testing to check for genetic mutations, which may also inform treatment.

Urothelial cancer is also described by grade (G) (see Table 3). The grade indicates how likely the cancer is to recur, grow or spread.

IDENTIFYING MUTATIONS
Diagnosing bladder cancer and determining the best treatment for your type may include genomic testing, which is performed on a sample of tumor tissue. It is used to examine a cancer’s genes to identify mutations that could indicate the cancer’s behavior, aggressiveness and whether it will metastasize.

In bladder cancer, genomic testing is increasingly being used to determine whether the tumor has certain targetable characteristics that would indicate which type of treatment may be most effective. If a mutation is found, your doctor will select a drug therapy that may target that specific mutation. However, not all mutations have approved treatments available.

Multiple gene mutations that contribute to bladder cancer have been discovered, and research is ongoing to find additional mutations that may affect the treatment or prognosis (outlook) of bladder cancer. Some of the common gene mutations found in bladder cancer include the following: ATM/RB1, ERCC2, FGFR2, FGFR3, HER2, HRAS, PIK3CA, TP53 and TSC1, among others. If the testing does not identify a specialized treatment, standard of care and clinical trials will be the options to consider.

Research has also identified some chromosome abnormalities that may play a role in bladder cancer. These abnormalities include variations in the number and structure of certain chromosomes. Partial or complete loss of chromosome 9 has been found to be associated with recurrence of low-grade bladder cancer. In addition, abnormal numbers of chromosomes 3, 7, 13 and 17 have been found in some bladder cancers.

SEEKING A SECOND OPINION
Getting a second opinion can ensure your diagnosis is accurate and can make you aware of clinical trials to consider. Doctors bring different training and experience to treatment planning. Some doctors may favor one treatment approach, such as a trial, while others might suggest a different combination of treatments.

Other specialists can confirm your pathology report and stage of cancer. They can also answer any additional questions you may have. Most doctors welcome a second opinion and will recommend another physician or hospital. Above all, the goal is for you to have the best care available.
Ron Speidel had no family history of cancer, so he was very surprised when at age 62, he was diagnosed with bladder cancer. He faced treatment the way he faced 30 years as a police officer — with no fear. But when his cancer metastasized and his treatment options ran out, his doctors told him to get his affairs in order. Months later, a clinical trial opened up and he joined. Today, his cancer is stable and he is living life to the fullest with his wife.

Face the challenge, then improvise, adapt & overcome

Feeling fatigued and taking three to four naps a day, instead of my normal one, was the only sign something was wrong. I told my doctor at my yearly physical but he chalked it up to getting older. The day I woke up and saw blood in my urine was when I knew something was wrong. I called my doctor immediately. After seeing the results, he called a urologist, and I had an appointment with him the next day.

The urologist performed a scope to examine my bladder, scrape off some of the lining and do a chemotherapy wash. When the doctor received the results, he said it was bladder cancer and that I would need a specialist because he had done all he could do for me. He called a well-known cancer center and within 20 minutes he had me scheduled with a specialist there.

The genitourinary medical oncologist performed his own scope to confirm the diagnosis. He said the cancer had broken through the muscular wall of my bladder. He recommended intravenous chemotherapy with the harshest regimen over 8 weeks to aggressively shrink the tumors followed by surgery. The surgery involved removing my bladder and prostate and creating an ileal conduit, which would allow my kidneys to drain urine that would exit through a small opening called a stoma. The side effects of the chemotherapy were challenging, but the surgeries went great. My 3-month and 6-month checkups were all good.

It took some time, but I gradually adapted to having a stoma. Some people have a hard time adjusting to it. Men fear they won’t be able to be intimate again and women fear they won’t be able to go out and do the things they used to. But if you look at me, you’d never know I had a bag on the side. Today, they make special undergarments for people with stomas so there won’t be any bulges. Having a stoma is not something to fear. It’s just a new normal.

A year after the surgery, follow-up testing showed the cancer had returned and metastasized to the bone. The oncologist said there was nothing more that could be done and to get my affairs in order because the prognosis was probably 6 months. He discussed pain medication for bone metastases and offered to help set me up with Hospice.

I was devastated. Even though I’d spent 30 years as a cop in high crime areas and had seen man’s inhumanity to man, I don’t get upset. But this news was shocking. I’d been healthy my whole life. I raced bicycles and went to college on an athletic scholarship.

Once I came to terms with the news, I decided to attack the cancer. I’ve always been a scrapper, and I was not going down without a fight! I asked about joining a clinical trial, but my doctor said there weren’t any at the time.

Three months later, that changed. The doctor called to ask whether I was still interested in joining a clinical trial that was starting soon. It planned to test a new drug therapy on bladder cancer. I figured I had nothing to lose and I thought if the doctors could learn something from me to help others, I wanted to do it.

I passed all the eligibility tests and was considered a very good candidate for the trial. Every 10 days my wife and I traveled several hundred miles to the hospital where the trial was being conducted to do blood draws, have scans, receive the treatment infusion and go to follow-up visits. At the end of the treatment, I showed no metastatic activity and was proclaimed “stable.” Eight years later, the treatment has kept the cancer under control. My activity level is back up to near normal. I’m just a bit slower now.

For men having surgery to remove the prostate, ask for the nerve-sparing surgery if possible so that you may be able to regain sexual function. I am still functional today, but without the hormones from my prostate, my libido has dropped. People ask whether you can have sex with a bag. It’s a little awkward at first, but my wife and I have adapted and found a way to work around it. Communication with your partner is so critical to make it work.

Facing cancer is scary, but I tell others not to ever give up. I live by the motto “Improvise, adapt and overcome.” There will be challenges that you will face, but you can become comfortable with the changes if you get into the right mindset. Try to fight, stay positive, don’t dwell on the bad, and listen to your doctors because they know what to do for you. If you have any bad habits, now is the time to quit. It is possible to survive cancer.

PatientResource.com
Advances in treatment strategies offer promise for people with bladder cancer and their loved ones. Through clinical trials, new and more effective options designed to treat and cure bladder cancer are becoming available. As you and your doctor discuss a treatment plan, make it a priority to share your expectations for your quality of life.

Flexibility and patience will become very important, especially if how you urinate changes. Learn as much as you can about the available options and practical ways to manage them. Talk with other bladder cancer survivors about their experiences. Hearing how someone has managed something similar can help you adopt a positive attitude and move forward more confidently. Use the resources in the back of this guide, and ask your medical team for additional referrals.

TREATMENT OPTIONS
To determine your treatment plan, your doctor considers the tumor's stage, grade and biomarker status; whether the cancer is non-muscle invasive or muscle-invasive; potential side effects; your general health; and your preferences concerning urine control.

Treatments can be used alone or in combination, and at different times. First-line therapy is the first treatment used. Second-line therapy is given when the first-line therapy does not work or is no longer effective. Standard of care refers to the most widely recommended treatments for the type and stage of cancer you have. Local treatments are directed at a specific organ or a limited area of the body and include surgery and radiation therapy. Systemic treatments are typically drug therapies, such as chemotherapy, immunotherapy and targeted therapy, which travel throughout the body.

Your treatment options may include the following.

Surgery is the primary method for treating a solid tumor. Removing it may offer the best chance of controlling the disease and keeping it from spreading, especially for early-stage disease. Surgery may also be used to stage the cancer or to relieve or prevent symptoms that occur later. A lymph node dissection may also be necessary to stage the cancer or to control cancer that is known to have spread to the nodes. Your doctor may elect to use one or more of the following procedures:

- Transurethral resection of bladder tumor (TURBT). A surgeon inserts a cystoscope through the urethra into the bladder and removes the tumor using an instrument with a small wire loop, a laser or high-energy electricity. TURBT may be used to diagnose, stage and treat bladder cancer.
- Cystectomy. A radical cystectomy removes the entire bladder and may also include nearby tissues or organs. Lymph nodes in the pelvis are also removed. In addition, men may have their prostate and urethra removed, and women may have their uterus, fallopian tubes, ovaries and part of the vagina removed. A partial (segmental) cystectomy may be performed to remove only a portion of the bladder, preserving the ability to urinate normally. In some cases, a cystectomy may be done laparoscopically or robotically.
- Urinary diversion. If your bladder is removed, another way to store and pass urine is necessary. You and your treatment team will determine which of the three types of diversion will work best for you (see Reconstruction, page 12).
  - An ileal conduit involves creating a new tube from a piece of intestine (ileum) to allow your kidneys to drain and exit through a small opening called a stoma.
  - A continent cutaneous pouch is a pouch inside your body made from a segment of your intestine that is attached to your ureters, allowing urine to be stored internally and then removed through a hole in your abdomen.
  - An orthotopic bladder, or neobladder, uses a portion of your intestine to connect the ureters to the urethra. It is sometimes referred to as a substitute bladder.

Drug therapy may include chemotherapy, immunotherapy or targeted therapy. Drug therapy may be used alone or combined with other types of treatment.

Chemotherapy uses drugs to kill rapidly multiplying cells throughout the body. Chemotherapy may be used before surgery (neoadjuvant therapy) or after surgery (adjuvant therapy).

To treat bladder cancer, chemotherapy is given intravesically or systemically.

- Intravesical (local) chemotherapy delivers drugs into the bladder through a catheter inserted through the urethra. Local treatment only destroys superficial tumor cells that come in contact with the chemotherapy solution. It cannot reach tumor cells

TREATMENT PLANNING
that have invaded the muscular layer of the bladder wall or tumor cells that have spread to other organs.

- Systemic chemotherapy is given intravenously (IV) through a small tube inserted into a vein or port (see Figure 1). It travels through the bloodstream.

Immunotherapy stimulates the immune system to find and attack cancer cells. Types of immunotherapy approved to treat bladder cancer include cytokines, immune checkpoint inhibitors, monoclonal antibodies (mAbs) and modified bacteria.

Cytokines aid in immune cell communication and play an important role in the full activation of an immune response. They are given intravenously.

Immune checkpoint inhibitors prevent the immune system from slowing down, allowing it to keep up its fight against the cancer. They are given intravenously. The immune checkpoint inhibitors approved for bladder cancer are mAbs. The mAbs are laboratory-made antibodies designed to target specific tumor antigens, which are certain proteins or other molecules on the surface of tumor cells that may trigger an immune response.

Modified bacteria, such as bacillus Calmette-Guérin (BCG), have been changed to reduce the likelihood that they will cause a harmful infection while stimulating an immune response. This therapy is given intravesically over multiple weeks (see Figure 2).

Targeted therapy uses drugs to identify and attack cancer cells. The types approved for bladder cancer include a kinase inhibitor and monoclonal antibodies (mAbs).

A kinase inhibitor may be used to treat some bladder cancers with a fibroblast growth factor receptor (FGFR2 or FGFR3) gene mutation. Data suggest that tumors with mutated FGFR3 are less likely to be recognized by the immune system, making targeted therapy an option for this gene mutation.

The approved mAbs are antibody drug conjugates (ADCs). ADCs consist of a mAb that is chemically linked to a chemotherapy drug (see Figure 3).

Chemoradiation therapy combines systemic chemotherapy and pelvic radiation therapy. It may be given after the bladder tumor is removed (using TURBT) or instead of surgery. This treatment approach is considered a bladder-preservation option because removal of the bladder may not be necessary if cancer is not detected after treatment. This therapy may be used for tumors that appear to have been completely removed by TURBT, invaded no deeper than the muscle wall and have not obstructed the ureter.

Radiation therapy uses high-energy radiation to destroy cancer cells and shrink tumors. It may be given with chemotherapy to relieve symptoms or to treat advanced disease. External-beam radiation therapy (EBRT) uses a machine outside the body to send radiation toward the cancer.

Clinical trials are medical research studies that may offer access to leading-edge treatments not yet widely available. Researchers are evaluating improved ways of diagnosing and treating bladder cancer, including improving how cystectomies and lymph node dissections are performed, identifying changes to genes or proteins that may lead to bladder cancer, and finding new types of drugs and drug combinations.

Let your team know whether you are open to considering a clinical trial. You can also search on your own (see Clinical Trials, page 13). Once you find a potential trial, talk with your doctor.

### DRUG THERAPIES FOR BLADDER CANCER

**CHEMOTHERAPY**
- cisplatin
- doxorubicin (Adriamycin)
- methotrexate
- mitomycin (Jemmyo, Mitozynex, Mutamycin)
- thiotepa (Tepadina)
- valrubicin (Valstar)

**IMMUNOTHERAPY**
- interferon (Roferon-A, Intron A, Alferon)
- immune checkpoint inhibitors
  - atezolizumab (Tencertix)
  - avelumab (Bavencio)
  - nivolumab (Opdivo)
  - pembrolizumab (Keytruda)
- modified bacteria
  - bacillus Calmette-Guérin (BCG)

**TARGETED THERAPY**
- kinase inhibitors
  - erdafitinib (Balversa)
- monoclonal antibodies
  - enfortumab vedotin-efjv (Padcev)
  - sacituzumab govetecan-hziy (Trodelyv)

**SOME POSSIBLE COMBINATIONS**
- carboplatin (Paraplatin) and gemcitabine (Gemzar)
- cisplatin and gemcitabine (Gemzar)
- Dose dense (DD)-MVAC (methotrexate, vinblastine [Velban, Velsar], doxorubicin [Adriamycin] and cisplatin)
- MVAC (methotrexate, vinblastine [Velban, Velsar], doxorubicin [Adriamycin] and cisplatin)
- pembrolizumab (Keytruda) + chemotherapy
- pembrolizumab (Keytruda) + chemotherapy + radiation

**RECURRENT BLADDER CANCER**
Bladder cancer that returns after treatment is called recurrent bladder cancer. The cancer may return in the same area as the primary cancer or in a different area of the body. It can happen weeks, months or even years after treatment stops, which is why a follow-up care regimen is so important.

If your bladder cancer returns, your doctor will recommend a series of tests to determine any changes in your type of cancer, whether it has spread and physical symptoms. A new treatment plan may be developed, and you may add finding a clinical trial to your plan.
Manage the effects of cancer and its various treatments

Advances have been made in treating cancer and also in ways to prevent and manage side effects. Your multidisciplinary health care team will use what’s known as supportive care services to address the physical, emotional, practical, spiritual and financial effects of your cancer diagnosis. Supportive care is designed to improve your overall well-being. Your family members, caregivers and others close to you can also benefit from these services.

You will work closely with a variety of specialists that may include an advanced practice nurse, physical therapist, spiritual advisor, dietitian or palliative medicine specialist who has extra training in symptom management.

### POTENTIALLY SEVERE SIDE EFFECTS

Although severe side effects are not common, they can occur with certain bladder cancer treatments. Ask your doctor whether any therapies in your treatment plan could cause them, and find out how to identify the symptoms. Report them immediately if they occur. Prompt medical attention can be lifesaving.

- **Infection** can occur as a result of a low white blood cell count (neutropenia) or other factors. Contact your doctor immediately – do not wait until the next day – if you have any of these symptoms: oral temperature over 100.4 °F; chills or sweating; body aches, chills and fatigue; coughing, shortness of breath or painful breathing; abdominal pain; sore throat; mouth sores; painful, swollen or reddened skin; pus or drainage from an open cut or sore; pain or burning during urination; pain or sores around the anus; or vaginal discharge or itching. If you cannot reach your doctor, go to the emergency room.

- **Immune-related adverse events (irAEs)** may occur with certain immunotherapy drugs if the immune system becomes overstimulated by treatment and causes inflammation in one or more organs or systems in the body. Some irAEs can develop rapidly, becoming severe and even life-threatening without immediate medical attention.

- **Infusion-related reactions** most frequently occur with treatments given intravenously (IV) through a vein in the arm and usually happen soon after exposure to the drug. Reactions are generally mild, such as itching, rash or fever. More serious symptoms, such as shaking, chills, low blood pressure, dizziness, breathing difficulties or irregular heartbeat, can be serious or even fatal without medical intervention.

### SOME COMMON SIDE EFFECTS

Some side effects are described in Table 1. They may be more intense when therapies are combined, and not every therapy leads to all these side effects. Talk with your health care team about any that need immediate attention and how to manage the less severe ones if they occur.

Treatment can also impact sexual desire and performance. For assistance, ask for a referral to an appropriate health care professional or support group. See Healthy Lifestyle, page 11.

### TABLE 1

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>Abnormally low red blood cell count</td>
</tr>
<tr>
<td>Bleeding in urine or stool</td>
<td>Blood that is visible after urinating or having a bowel movement</td>
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<tr>
<td>Blood clots</td>
<td>Leg discomfort</td>
</tr>
<tr>
<td>Bowel incontinence</td>
<td>Stool leakage caused by the inability to control bowel movements</td>
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<tr>
<td>Bruising or bleeding</td>
<td>Low number of platelets in the blood (thrombocytopenia)</td>
</tr>
<tr>
<td>Chemo brain (cognitive dysfunction)</td>
<td>Brain fog, confusion and/or memory problems</td>
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<tr>
<td>Constipation</td>
<td>Difficulty passing stools or having less frequent bowel movements compared to usual bowel habits</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>Eating less than usual, feeling full after minimal eating, not feeling hungry</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>Frequent loose or watery bowel movements that are commonly an inconvenience but can become serious if left untreated</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>Inability to have an erection adequate for sexual intercourse</td>
</tr>
<tr>
<td>Eye and vision problems</td>
<td>Blurred vision, dry eyes, eye pain, loss of vision</td>
</tr>
<tr>
<td>Fatigue</td>
<td>Tiredness that is much stronger and harder to relieve than the fatigue an otherwise healthy person has</td>
</tr>
<tr>
<td>Infertility</td>
<td>Inability to become or stay pregnant or to father a child</td>
</tr>
<tr>
<td>Lymphedema</td>
<td>Fluid buildup from lymph node removal that causes swelling</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>The feeling of needing to throw up and/or throwing up</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>Numbness, pain, burning sensations and tingling, usually in the hands or feet at first</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>Low white blood cell count that increases the risk of infection</td>
</tr>
<tr>
<td>Pain</td>
<td>Pain and aches that occur in the muscles, bones, tendons, ligaments or nerves</td>
</tr>
<tr>
<td>Respiratory problems</td>
<td>Shortness of breath (dyspnea) with or without cough, upper respiratory infections</td>
</tr>
<tr>
<td>Sexual dysfunction</td>
<td>Erectile dysfunction, reduced desire or feeling less desirable, vaginal dryness, pain during intercourse</td>
</tr>
<tr>
<td>Skin reactions</td>
<td>Rash, redness and irritation, or dry, flaky or peeling skin that may itch</td>
</tr>
<tr>
<td>Urinary discomfort</td>
<td>Pain or burning when urinating</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>Inability to control the flow of urine from the bladder</td>
</tr>
<tr>
<td>Urinary retention</td>
<td>Inability to completely empty the bladder (bladder may feel full even after urinating)</td>
</tr>
<tr>
<td>Weight loss</td>
<td>Losing weight without trying</td>
</tr>
</tbody>
</table>
Navigating the physical and emotional impacts of bladder cancer

Whether you are just starting treatment for bladder cancer, actively managing it or in maintenance, adopting a healthy lifestyle can benefit you in multiple ways. It may help you tolerate treatment better, lower the risk of a recurrence, help protect against secondary cancers and support your mental and emotional well-being.

Diet and Exercise
Eating a nutritious diet, maintaining a healthy weight, limiting alcohol, exercising and avoiding tobacco use are all positive choices. Experts recommend a diet high in vegetables and fruits, whole grains, and lean protein. Weight can fluctuate during treatment. A diettian can help tailor an eating plan for you.

Exercise and physical activity are effective for managing fatigue, maintaining a healthy weight, boosting muscle strength and endurance, and improving self-esteem and your mental health.

Moving Forward After Diagnosis
Your daily activities after bladder cancer may not be the same as before treatment. Certain adjustments will be needed. If you had bladder surgery, you may have to change how you urinate and bathe, especially if you have a stoma. You may find it valuable to connect with other people who have had the same type of surgery as you through peer-to-peer matching services and online or in-person support groups. They will have suggestions and ideas that are helpful. Following are possible issues you may face.

Incontinence is a common side effect of bladder cancer treatment. Difficulty with urination may happen when all or part of the bladder has been removed or with chemotherapy, radiation therapy and immunotherapy. Ways to make you more comfortable may include the following:

- Pelvic floor exercises, commonly known as Kegels (pronounced KEE-gulz), can help reduce leakage from stress incontinence (see About Kegels).
- Medications that can tighten or relax your muscles may be prescribed. These drugs can have side effects, so make sure to ask about them.
- For incontinence caused by blockage of the urethra by scar tissue or by an enlarged prostate, a surgical procedure done through a scope can relieve the obstruction.

Sexual dysfunction may occur as a result of surgery, radiation to the pelvic area or hormone therapy that suppresses or removes reproductive organs. Some effects may include erectile dysfunction, infertility, lack of desire and painful intercourse, as well as fatigue, mood changes and feeling insecure.

For men, erectile dysfunction (ED), which is the inability to achieve or maintain an erection, is one of the most common side effects of cancer treatment in the pelvic area, including the bladder, prostate, rectum and urethra. ED can be caused by several factors:

- Damage during treatment to nerves or blood vessels that supply the penis.
- Reduced level of testosterone in the blood resulting from hormone therapy or other injury or damage to the testicles, which produce testosterone.

Multiple options are available to treat ED. These include oral medications, penile injections, urethral suppositories, vacuum constriction devices and penile prostheses or implants.

For women, removing the bladder as well as the ovaries can bring on premature menopause. As a result, lower hormone levels may lead to menopausal symptoms, reduced libido (sex drive), inability to achieve or maintain arousal, vaginal dryness, pain during intercourse or the delay or absence of orgasm.

Multiple remedies include hormone replacement therapy, moisturizers to relieve vaginal dryness, lubricants to reduce pain during intercourse and vaginal dilators to gradually stretch the walls of the vagina to increase comfort during intercourse.

Infertility is the inability to become or stay pregnant or to father a child. Although most people with bladder cancer are over 55, bladder cancer can develop in people of childbearing age. If having a child is in your future, consult with your medical team and a fertility expert before committing to any treatment options, if possible.

Emotional Effects
The physical effects caused by bladder cancer and its treatment may affect your mental and emotional health, self-esteem and body image. Physical changes may make you feel insecure, causing intimacy to be challenging. Cancer and its treatment can affect how you feel about yourself and your body and how you relate intimately to your partner. You and your partner should share your concerns and fears with each other.

Various holistic approaches may improve self-esteem and body image following bladder cancer, as well as reduce feelings of depression and increase the overall sense of well-being. These may include journaling, meditation and group therapy using guided imagery.

Follow-Up Care
Keeping ongoing appointments is crucial. In addition to addressing the above concerns, it is important to be alert for recurrence. Early detection can improve prognosis.

About Kegels

Exercises to help manage incontinence

Kegels are helpful before and after bladder cancer treatment. These exercises may not eliminate your bladder incontinence, but with consistent practice, you could see a marked improvement in just weeks. Do not practice them if you have a catheter in place.

To get started, try to perform these exercises while you are standing. If you are not able to stand, try sitting or choose a position that is comfortable for you.

1. Tighten your pelvic floor muscles. Ensure you’re flexing the correct muscles (not your abdomen, thighs, or buttocks). Tighten the muscles used to stop urinating mid-flow.

2. Hold the contraction for 10 seconds, and then relax for 10 seconds. Avoid holding your breath. Instead, breathe freely during the exercises.

3. Aim for at least six sets of 10 repetitions a day. As your muscles get stronger, increase your repetitions daily.
**Explore your options for urinary diversion**

A reconstructive operation is necessary following the surgical removal of the bladder (radical cystectomy) to establish a way to store urine and empty it. There are three possible types of reconstruction: an ileal conduit, a continent cutaneous pouch and an orthotopic bladder (neobladder). All procedures involve part of the intestine being surgically transformed into part of a system that allows urine to be stored and to exit the body in the typical way or through a stoma, an opening that is created surgically through the skin (see Figure 1).

**ILEAL CONDUIT**
An ileal conduit is the most common type of reconstructive surgery performed on patients who have had a radical cystectomy. This surgery involves using a piece of the ileum, the end section of the small intestine, to create a pouch to hold the urine and from which it can be expelled. At the time of surgery, the following steps to construct an ileal conduit or ileostomy are also taken. The surgeon isolates a piece of intestine (ileum) while making sure blood vessels are still supplying the intestine. The surgeon stitches the ends of the ileum from which the isolated pieces has been removed, restoring the integrity of the bowel.

The surgeon then attaches the ureters (tubes through which urine normally flows from the kidney to the bladder) to the end of the surgically isolated intestine. Then the other end of the piece of ileum is attached to your skin through an incision in your abdominal wall, called a stoma. The stoma empties urine into a bag taped or glued to your abdominal wall. This option allows urine to flow continuously through the new conduit to the outside, where it is collected in a small bag called an ostomy bag. This bag is attached to the stoma and is emptied periodically. The pouch lies flat against the body, and can be covered with clothes. This surgery is classified as an incontinent diversion because you no longer control the flow of urine from the body.

**CONTINENT CUTANEOUS POUCH**
Another option is a continent cutaneous pouch. This diversion involves an internal storage container for urine, which is made from a section of intestine attached to the ureters. This container, also referred to as an Indiana pouch, is folded and then connected to a stoma on one end with the ureters on the other. The pouch is drained by inserting a small, string-like tube known as a catheter through the stoma. It is crucial that the skin surrounding the stoma is washed and dried prior to and following each catheterization.

This type of diversion allows for some control over dispelling urine. In the weeks following the procedure, the pouch will need to be drained every two to three hours.

**ORTHOTOPIC BLADDER (NEOBLADDER)**
The third option for reconstructive surgery is an orthotopic bladder, also known as a neobladder. This is created using a small portion of your intestine (usually the ileum) that acts as an internal reservoir for storing urine. One end is attached to the ureters, while the other is attached to the urethra, the part of your body through which urine exits. A collection bag is not needed, and urine is able to leave your body in the regular way.

During the healing process, urine will be drained through a catheter or stents (small mesh tubes), which are placed into the neobladder through a small incision in the abdomen. Though you initially will not have control over when urine flows, over time, you may be able to have some control. The catheter also serves to remove mucus, an important step of maintaining hygiene throughout the reconstructive process.

**What is a stoma?**
A stoma is a word used for any opening in the body. Any hollow organ can be surgically made into a stoma. When undergoing a urostomy or treatment for bladder cancer, a stoma will be made in your abdomen and connected to your urinary system. A barrier ring can be used to fill in any gaps. A pouch will be attached to your stoma, which serves to collect urine.

Though having a stoma may take some getting used to, remember that most people are able to resume their daily lifestyles, as well as wear the same clothes. Talk with your ostomy nurse about your concerns and ask for any advice that may help you adjust. These additional suggestions may help:

- Wash your hands with soap and water before and after caring for your stoma and pouch.
- Keep the area around your stoma clean by using water and patting dry.
- Changing the pouch regularly helps avoid leaks and skin irritation. Getting used to changing your pouch is incredibly helpful and an important part of keeping yourself comfortable.
- Shaving the area around the pouch will help the pouch stick better to skin.
- Pouches include filters that help prevent odors. Using fragrance drops or sprays to further mask the odor may boost your confidence.

**FIGURE 1**
BLADDER REMOVAL AND RECONSTRUCTION

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**Ileal conduit**

- Kidneys
- Ureters
- Segment of intestine
- Stoma (outside body)

**Continent cutaneous pouch (Indiana pouch)**

- Kidneys
- Ureters
- Pouch (inside body)
- New bladder

**Orthotopic bladder (neobladder)**

- Kidneys
- Ureters
- Stoma (outside body)
Support and financial resources available for you

**BLADDER CANCER**
- American Bladder Cancer Society: www.bladdercancersupport.org
- Bladder Cancer Advocacy Network: www.bcan.org
- United Ostomy Associations of America, Inc.: www.ostomy.org

**CAREGIVERS & SUPPORT**
- Cactus Cancer Society: www.cactuscancer.org
- CanCare: www.canercare.org, 800-813-4673
- Cancer Connection: www.cancerconnection.org, 413-586-1642
- Cancer Hope Network: info@cancerhopenetwork.org, 877-467-3838
- Cancer Really Sucks!: www.cancerreallysucks.org
- Cancer Support Community: www.cancersupportcommunity.org, 888-793-9355
- Cancer Survivors Foundation: www.cancer.org, 800-227-2345
- Caregiver Action Network: www.caregiveraction.org, 855-277-3640
- CaringBridge: 851-788-2300
- Center to Advance Palliative Care: www.capc.org, 347-835-0658
- Chemo Angels: www.chemoangels.com
- Cleaning for a Reason: www.cleaningforareason.org
- Connect Thru Cancer: www.connectthru癌.org, 484-301-3047
- Cooking with Cancer: www.cookingwithcancer.org, 205-978-3570
- Family Caregiver Alliance: www.caregiver.org, 800-445-8106
- The Gathering Place: www.touch gearbox.org, 216-595-9546
- Imamorg: www.iman.org
- Livestrong Foundation: www.livestrong.org, 855-220-7777
- Living Hope Cancer Foundation: www.getupandlive.org
- LivingWell Cancer Resource Center: www.livewellcancer.org, 630-933-7880
- Lotsa Helping Hands: www.lotsahepelpinghands.com
- The Lydia Project: www.thelydiaproject.org, 877-593-4212
- MyLifeLine: www.mylifeline.org, 888-793-9355
- National LGBT Cancer Project: www.lgbtcancer.org, 833-213-6657
- Patient Empowerment Network: www.patientpowerpartners.org, 888-213-6657
- SHARE Caregiver Circle: www.sharesupport.org, 844-275-7427
- Stronghold Ministry: www.mystronghold.org, 877-230-7674
- Triage Cancer: www.triagecancer.org, 424-258-4628
- Walk With Sally: www.walkwithsally.org, 310-322-3900
- WellSpouse Association: www.wellspospouse.org, 723-577-8989
- weSPARK Cancer Support Center: www.wespark.org, 818-906-3022
- Wigs & Wishes: www.wigsandwishes.org, 856-582-6600

**CLINICAL TRIALS**
- Cancer Support Community: www.cancersupportcommunity.org/find-clinical-trial, 888-793-9355
- Center for Information & Study on Clinical Research Participation: www.searchclinicaltrials.org, 877-633-4376
- ClinicalTrials.gov: www.clinicaltrials.gov
- Lazarex Cancer Foundation: www.lazarex.org, 877-866-9523
- National Cancer Institute: www.cancer.gov, 800-422-6231
- NCIC Cancer Information Service: www.ncicic.org, 800-422-6231
- WCG CenterWatch: www.centerwatch.com, 866-219-3440

**GOVERNMENT ASSISTANCE**
- Benefits.gov: www.benefits.gov
- Centers for Medicare & Medicaid Services: www.cms.gov
- Disability Benefits Center: www.disabilitybenefitcenter.org
- Eligibility.com: www.eligibility.com
- Legal Services Corporation: www.lsc.gov, 202-295-1500
- Medicare Rights Center: www.medicarights.org, 800-333-4114
- National Council on Aging: www.ncoa.org, 571-527-3900
- Social Security Administration: www.ssa.gov, 800-772-1213
- State Health Insurance Assistance Programs: www.shifelp.org
- U.S. Department of Veterans Affairs: www.va.gov/health

**NUTRITION**
- American Cancer Society: www.cancer.org, 800-227-2345
- CancerCare: www.cancercare.org, 800-813-4673
- Cancer Support Community: www.cancersupportcommunity.org, 888-793-9355

**PATIENT ADVOCACY**
- American Cancer Society: www.fightcancer.org, 202-681-5700
- Cancer Legal Resource Center: www.theclic.org, 212-487-2106
- Cancer Support Community: www.cancersupportcommunity.org, 888-793-9355
- Dream Foundation: www.dreamfoundation.org, 888-437-3267
- Firefighter Cancer Support Network: www.firefightercancersupport.org, 866-994-3276
- The Gathering Place: www.touch gearbox.org, 212-595-9546
- Gens of Hope, Inc.: www.gensofhope.com, 319-393-9981
- LivingWell Cancer Resource Center: www.livingwellcancer.org, 630-933-7880
- National Coalition for Cancer Survivorship: www.canceradvocacy.org
- Office of Cancer Survivorship: www.cancer.gov, 800-422-6237
- Patient Advocacy Foundation: www.patientadvocate.org, 800-532-5274
- Research Advocacy Network: www.researchadvocacy.org, 877-276-2187

**REIMBURSEMENT & PATIENT ASSISTANCE PROGRAMS**
- Astellas Pharma Support Solutions: www.astellaspharmsupportsolutions.com, 800-477-6472
- Balversa Janssen CarePath: www.janssencarespath.com/balversa, 877-227-3728
- Bavencio CoverGine: www.covergine.com, 888-769-6371
- Bristol-Myers Squibb Patient Access Support: bmsaccesssupport.bmscustomercareconnect.com, 800-861-0041
- Bristol-Myers Squibb Patient Assistance Foundation: bmsfoundation.com, 800-736-0003
- Genentech Oncology Co-pay Assistance Program: www.coopaysupport.com, 888-692-6729
- Janssen CarePath: www.janssencarespath.com, 877-227-3728
- Johnson & Johnson Patient Assistance Foundation: www.jnjpf.com, 800-652-6277
- Keytruda KEY-YOU: www.keytrudacom, 855-388-7832, press 2
- Merck Access Program: www.merckaccessprogram.com
- Merck Patient Assistance Program: www.merckhelps.com, 877-724-5000
- Otexup Total Care Support Program: www.otexup.com/patient-resources, 888-422-5604
- Padcev Support Solutions: www.padcev.com/padcev-support-solutions, 888-402-9627
- Pfizer Oncology Together: www.pfizeroncologytogether.com, 877-744-5675
- Raveo CORE Connections: www.raveo.com/patient-resources, 855-336-3322
- Seagen Support: www.seagen.com/patient-support-and-resources
- Tecentriq Access Solutions: www.tecentriqaccess.com, 877-436-3833
- Trodelvis Access Support: www.trodelvic.com, 844-876-3383, option 2

**SURVIVORSHIP**
- 13thirty Cancer Network: www.13thirty.org
- A Time to Heal Cancer Foundation: www.atimetohalffoundation.org, 402-401-6083
- Angel On My Shoulder: www.angelonmyshoulder.org
- American Cancer Society: www.cancer.org
- Cactus Cancer Society: www.cactuscancer.org
- Cancer ABCs: www.cancerabc.org, 516-445-2026
- Cancer and Careers: www.cancerandcareers.org, 646-929-8032
- Cancer Survivors Network: www.cancersurvivors.org, 800-227-2345
- Global Resource for Advancing Cancer Education (GRACE): www.cancergrace.org
- Indian American Cancer Network: www.iaacnetwork.org
- Livestrong Foundation: www.livestrong.org
- National Cancer Survivors Day: www.ncsd.org, 615-794-3906
- National Coalition for Cancer Survivorship: www.canceradvocacy.org
- River Discovery: www.riverdiscovery.org
- Stupid Cancer: www.stupidcancer.com, 212-619-1040

**For more resources, go to:** PatientResource.com