Advanced* Bladder Cancer

Talking About PADCEV®: A Guide to Conversations About Treatment

*Cancer that has spread or cannot be removed by surgery.

The questions in this guide can help you have more effective conversations with your healthcare team and can help you get the answers that matter most to you.

Being open and honest with your healthcare team during your conversations can help them make the best decisions about your treatment plan.

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).

- PADCEV may be used with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph when your bladder or urinary tract cancer has spread or cannot be removed by surgery (locally advanced or metastatic).
- PADCEV may be used alone when your bladder or urinary tract cancer has spread or cannot be removed by surgery (locally advanced or metastatic) if you:
  - have received PD-1 or PD-L1 immunotherapy medicine **and** chemotherapy that contains platinum, **or**
  - are not able to receive a chemotherapy that contains cisplatin **and** you have received 1 or more prior therapies.

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

IMPORTANT SAFETY INFORMATION

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

PADCEV may cause serious side effects, including:

Skin reactions. Skin reactions including severe skin reactions have happened in people treated with PADCEV and may be more common when PADCEV is given with pembrolizumab. In some cases, these severe skin reactions have caused death. Most severe skin reactions occurred during the first cycle 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.

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See **"What are the possible side effects of PADCEV?"** for more information about side effects.

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 3 weeks after the last dose of 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.

What are the possible side effects of PADCEV?

PADCEV may cause serious side effects, including:

- **Skin Reactions. See "What is the most important information I should know about PADCEV?"**
- **High blood sugar (hyperglycemia).** An increase in blood sugar is common during treatment with PADCEV. Severe high blood sugar, a serious condition called diabetic ketoacidosis, and death have happened in people with and without diabetes treated with PADCEV. Tell your healthcare provider right away if you get any symptoms of high blood sugar, including: 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.
- **Lung problems.** PADCEV may cause severe or life-threatening inflammation of the lungs that can lead to death. These severe problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.
- **Nerve problems.** Nerve problems, called peripheral neuropathy, are common during treatment with PADCEV and can sometimes be severe. Nerve problems may happen more often when PADCEV is given in combination with pembrolizumab. Tell your healthcare provider right away if you get new or worsening numbness or tingling in your hands or feet or muscle weakness.
- **Eye problems.** Certain eye problems are common during treatment with PADCEV. Tell your healthcare provider right away if you get dry eyes, increased tearing, blurred vision, or any vision changes. You may use artificial tear substitutes to help prevent or treat dry eyes.

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IMPORTANT SAFETY INFORMATION (CONT'D)

- **Leakage of PADCEV® out of your vein into the tissues around your infusion site (extravasation).** If PADCEV leaks from the injection site or the vein into the nearby skin and tissues, it could cause an infusion site reaction. These reactions can happen right after you receive an infusion, but sometimes may happen days after your infusion. Tell your healthcare provider or get medical help right away if you notice any redness, swelling, itching, blistering, peeling skin or discomfort at the infusion site.

Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV if you get severe side effects.

If your healthcare provider prescribes PADCEV in combination with the medicines pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, also read the Medication Guide that comes with these medicines for additional important information.

The most common side effects of PADCEV when used in combination with pembrolizumab include:

- Changes in liver function and kidney function tests
- Rash
- Increased sugar (glucose) in the blood
- Numbness or tingling in your hands or feet
- Increased lipase (a test done to check your pancreas)
- Decreased white blood cell, red blood cell, and platelet counts
- Tiredness
- Decreased sodium, phosphate, and protein (albumin) in the blood
- Itching
- Diarrhea
- Hair loss
- Decreased weight
- Decreased appetite
- Increased uric acid in the blood
- Increased or decreased potassium
- Dry eye
- Nausea
- Constipation
- Change in sense of taste
- Urinary tract infection

The most common side effects of PADCEV when used alone include:

- Increased sugar (glucose) in the blood
- Changes in liver and kidney function tests
- Decreased white blood cell, red blood cell, and platelet counts
- Rash
- Tiredness
- Numbness or tingling in your hands or feet
- Decreased protein (albumin), sodium, and phosphate in the blood
- Hair loss
- Decreased appetite
- Diarrhea
- Nausea
- Itching
- Increased uric acid in the blood
- Dry eye
- Change in sense of taste
- Constipation
- Increased lipase (a blood test done to check your pancreas)
- Decreased weight
- Stomach (abdominal) pain
- Dry skin

PADCEV may cause fertility problems in females and males, which may affect the ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of PADCEV.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch**.

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IMPORTANT QUESTIONS YOU MAY WANT TO ASK YOUR HEALTHCARE TEAM

Below are some suggested questions to discuss with your healthcare team, along with space to take notes during your visit. Feel free to use these as a starting point, and don't hesitate to ask any other questions that come to mind.

What should I expect from treatment with PADCEV®?

How will I know if this treatment is working for me?

How many times a month will I need to go to the clinic, infusion center, or doctor's office for my treatment?

INFORMATION ABOUT PADCEV

Visit the FAQ page at PADCEV.com/advanced-bladder-cancer/frequently-asked-questions and find out more about treatment with PADCEV. Please note, any and all questions regarding PADCEV should be discussed with your healthcare team

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IMPORTANT QUESTIONS YOU MAY WANT TO ASK YOUR HEALTHCARE TEAM (CONT'D)

How will this treatment affect my daily life?

What factors should I consider when choosing my treatment plan, such as side effects, frequency of office visits, or who will be on my care team?

Once we decide on a treatment plan, what other steps should I take with my care team or family?

Will I need help at home during treatment, and what kind of support should I plan for?

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IMPORTANT QUESTIONS YOU MAY WANT TO ASK YOUR HEALTHCARE TEAM (CONT'D)

Is my treatment plan covered by insurance, and where can I find financial support if needed?

When do side effects usually occur? Do some side effects occur earlier than others?

How could side effects impact my treatment?

If I experience a side effect, how should I report it and whom should I report it to?

TREATMENT RESOURCES

Visit PADCEV.com/advanced-bladder-cancer/resources for more information about your treatment, including downloadable resources like a symptom tracker, to help you stay organized and make the most of each office visit

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PADCEV® QUESTIONS FOR CAREGIVERS

Caregivers play an important part in helping patients on their treatment journeys. Caregivers should discuss subjects such as these with the patient's healthcare team to see how they can best support their loved one and themselves.

Will we need help at home during treatment, and what kind of support should I plan for?

Is there financial support that you can connect us with?

Is there a website or other materials where I can learn more about PADCEV, advanced bladder cancer and cancers of the urinary tract,* and supporting my loved one through treatment?

*Renal pelvis, ureter, or urethra.

Additional notes

CAREGIVER RESOURCES

Visit the Tips for Caregivers page at PADCEV.com/advanced-bladder-cancer/caregiver-tips for suggestions and resources that may be helpful as you support your loved one throughout their treatment journey

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PADCEV Support Solutions® is here to help

The Patient Connect Program, part of PADCEV Support Solutions, may be able to help connect you and your loved ones to educational resources and support based on your particular needs.*

For more information, call PADCEV Support Solutions at 1-888-402-0627 Monday-Friday, 8:30 AM to 8:00 PM ET

For more information about PADCEV® and to download additional treatment resources, please visit PADCEV.com/advanced-bladder-cancer

*Support is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas or Pfizer. Availability of support and eligibility requirements are determined by these organizations.

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Please see Important Safety Information throughout and read the Patient Information here for more information, including risk of Serious Side Effects.