TALKING ABOUT PADCEV®:
A guide to conversations about treatment

*Cancer that has spread into the muscle layer of the bladder but not to other parts of the body.

PADCEV + pembrolizumab (Keytruda®) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™) is approved to treat muscle-invasive bladder cancer in adults before and after bladder removal surgery.

Whether you have recently been diagnosed with MIBC or are preparing for surgery, you may have questions about what comes next. This guide can help you discuss PADCEV with your healthcare team and ask questions so that you can get the answers that matter most to you. Each page of this guide has space for you to write down answers, next steps, or anything else you may want to remember during your visit.

Being open and honest with your healthcare team during these conversations can help them make informed decisions about your treatment plan, both before and after surgery.

WHAT IS PADCEV (enfortumab vedotin-ejfv)?

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 before and after the surgical removal of your bladder when your bladder cancer has spread into the muscle layer of the bladder (muscle invasive bladder cancer [MIBC]) but not to other parts of the body.

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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Injection for IV infusion 20 mg & 30 mg vials

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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.

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Important Safety Information (cont'd)

- **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.
- **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 each of 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

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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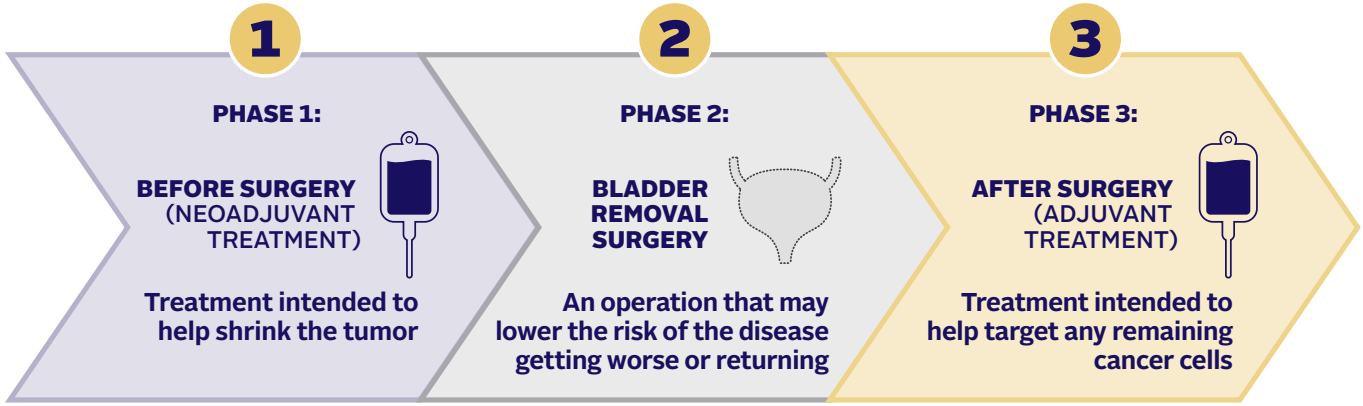
Understanding treatment before and after your surgery

- **Before surgery (neoadjuvant):** Treatment intended to help shrink the cancer
- **After surgery (adjuvant):** Even when the bladder is removed, cancer cells can still be present. The goal of adjuvant treatment is to help target those cells

Treatment with PADCEV® may also target healthy cells, which may result in side effects

TREATMENT IS GIVEN BEFORE AND AFTER SURGERY



Why is treatment before bladder removal surgery an important part of my treatment plan?

If my bladder is removed, why might I still need treatment afterward?

FOR MORE CAREGIVER RESOURCES, visit the **Tips for Caregivers** page at **PADCEV.com/mibc/caregiver-tips** to find information that may be helpful as you support your loved one throughout their treatment journey.

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Please see Important Safety Information on pages 1-3 and read the Patient Information here for more information, including risk of Serious Side Effects.

Important questions you may want to ask about what to expect from treatment

How do I know if treatment with PADCEV® + pembrolizumab (Keytruda®) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™), given before and after surgery, is right for me?

What is the overall treatment timeline for PADCEV + pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph when given before and after surgery, and how often will I receive each treatment?

What are the potential side effects of treatment? Are some more common than others?

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

TREATMENT RESOURCES

Visit **PADCEV.com/mibc/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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Important questions you may want to ask about treatment—before and after bladder removal surgery

What can I do to prepare for life after bladder removal surgery?

Is there anything I need to know about the transition period between surgery and treatment after surgery (adjuvant treatment)?

What happens if surgery is delayed or recovery takes longer than expected?

FOR MORE INFORMATION ABOUT PADCEV®, visit **PADCEV.com/mibc**. 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 about finding support and navigating life during treatment

How will this treatment affect my daily life?

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

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

What support or advocacy groups are available for people like me?

EXPLORE SUPPORT AND FINANCIAL ASSISTANCE OPTIONS: Go online to PADCEV.com/padcev-support-solutions to find out more about services offered by PADCEV Support Solutions® such as financial assistance, insurance coverage, and other resources that may help you access treatment.

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Questions for caregivers to ask the healthcare team

As a caregiver, you can play an important part in supporting your loved one's treatment journey. Here are some suggested questions to ask the healthcare team, with space to jot down notes.

When it is time for bladder removal surgery, what should I expect in terms of hospital stay, recovery time, and follow-up care after surgery, and how can I best support my loved one during that period?

What kind of help will be needed at home during treatment and after surgery, and how can I best prepare for it?

Where can I find resources about PADCEV®, MIBC, and how to support my loved one throughout their treatment?

What financial support programs are available to help manage the costs of surgery and treatment?

FOR MORE CAREGIVER RESOURCES, visit the **Tips for Caregivers** page at **PADCEV.com/mibc/caregiver-tips** to find information 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 one 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**

*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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