

Getting started with PADCEV[®] (enfortumab vedotin-ejfv)

This brochure includes information about what PADCEV is and how it helped some patients. It may be helpful for you to review this brochure with your healthcare team, who can further explain how PADCEV is thought to work and why it might be the right treatment for you.

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 with pembrolizumab (also known as Keytruda[®]), **or**
- PADCEV may be used alone if you:
 - have received an immunotherapy medicine **and** chemotherapy that contains platinum, **or**
 - are not able to receive a chemotherapy that contains the medicine cisplatin **and** you have received 1 or more prior therapy.

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.

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

 **PADCEV**[®]
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

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Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.



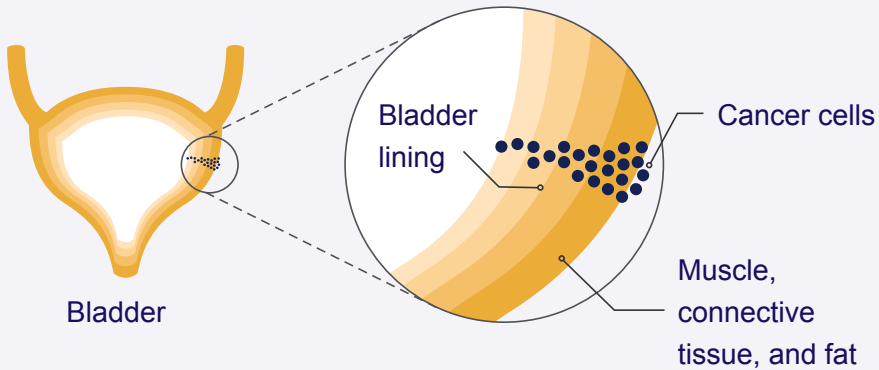
About advanced bladder cancer

What are advanced bladder cancer and cancers of the urinary tract?

Urothelial (bladder) cancer begins in the cells lining the organs (bladder, ureters, renal pelvis, and urethra) in the urinary system. When the cancer spreads to nearby areas, it is called **locally advanced cancer**. If it has spread to distant parts of the body, like the lymph nodes or other organs, it is called **metastatic cancer**.

Bladder cancer that has spread or cannot be removed with surgery is known as *advanced bladder cancer*.

How cancer spreads through the bladder



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How is advanced bladder cancer treated?

There are different treatment options for people who have been diagnosed with advanced bladder cancer depending on the stage of the disease and how they respond to treatment. You and your doctor will work together to decide which treatment is best for you.

Treatments might include:

- **Antibody-drug conjugate (ADC):** A type of targeted therapy that works by delivering cell-killing medicine directly to cancer cells. However, it can also affect normal cells and cause side effects
- **Chemotherapy:** Treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. This can affect cancer cells and normal cells. Platinum-based chemotherapy, such as **cisplatin** or **carboplatin**, in combination with gemcitabine is a treatment option for advanced bladder cancer
- **Clinical trial:** A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called clinical study
- **Immunotherapy:** Treatment that uses substances to stimulate or suppress the immune system to help the body fight cancer
- **Radiation therapy:** Treatment that uses energy in the form of particles or electromagnetic waves to kill cancer cells and shrink tumors
- **Surgery:** A procedure to remove a part of the body where cancer cells are present

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Who is PADCEV® for?

PADCEV can be used by itself or together with pembrolizumab (Keytruda®) to treat advanced bladder cancer

Whether your doctor prescribes PADCEV alone or in combination with pembrolizumab depends on your bladder cancer treatment history.

Ask your doctor which study group best represents your condition.

For people who had not yet received a treatment for advanced bladder cancer:

See how PADCEV was shown to help in combination with pembrolizumab



[Jump to pg 8-9](#)

For people who previously received an immunotherapy medicine and cisplatin- or carboplatin-containing chemotherapy:

See how PADCEV given alone was shown to help



[Jump to pg 11-12](#)

PADCEV was studied in additional groups of people. Learn more at **[PADCEV.com](#)**.

SELECT SAFETY INFORMATION

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.

Please see Important Safety Information throughout and **[read the Patient Information](#)** for more information, including risk of **Serious Side Effects**.



What is PADCEV®?

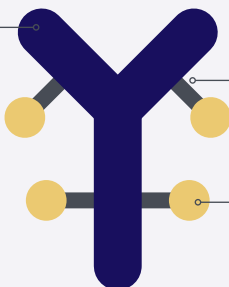
PADCEV is used to treat advanced bladder cancer

It is a type of prescription medicine known as an antibody-drug conjugate, or ADC.

- PADCEV is different from the chemotherapy or immunotherapy you may have had before
- PADCEV is thought to work by delivering cell-killing medicine directly to certain cancer cells.* However, it can also affect normal cells and cause side effects
- Talk to your healthcare professional about side effects, and see [pages 15-17](#) for information about possible side effects with PADCEV

PADCEV is made of 3 parts:

An **antibody** that attaches to a certain type of protein on the surface of a cell



A **link** that connects the cell-killing medicine to the antibody

Cell-killing medicine that is released inside of the cell

*This is how PADCEV was shown to work in lab studies.

 **Antibody:** A protein most commonly made by the body's immune system. The antibody that makes up PADCEV is produced in a laboratory.

SELECT SAFETY INFORMATION

Females who are able to become pregnant:

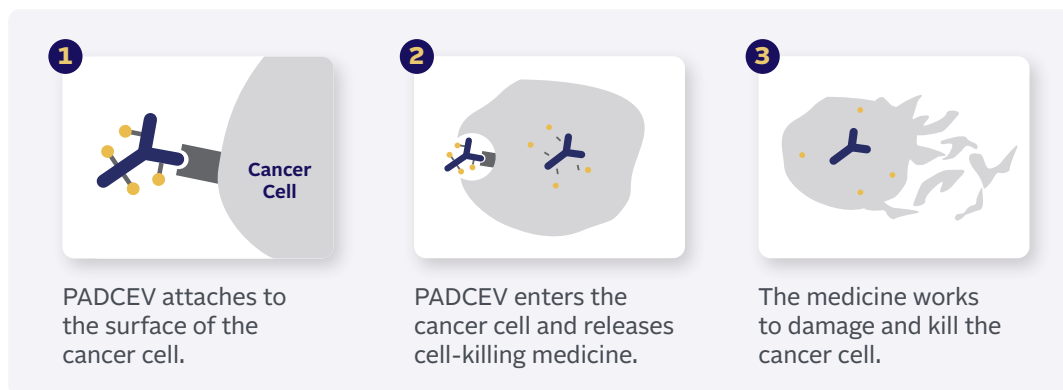
- Your healthcare provider should do a pregnancy test before you start treatment with PADCEV.
- You should use an effective method of birth control during your treatment and for at least 2 months after the last dose of PADCEV.

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How PADCEV® is thought to work

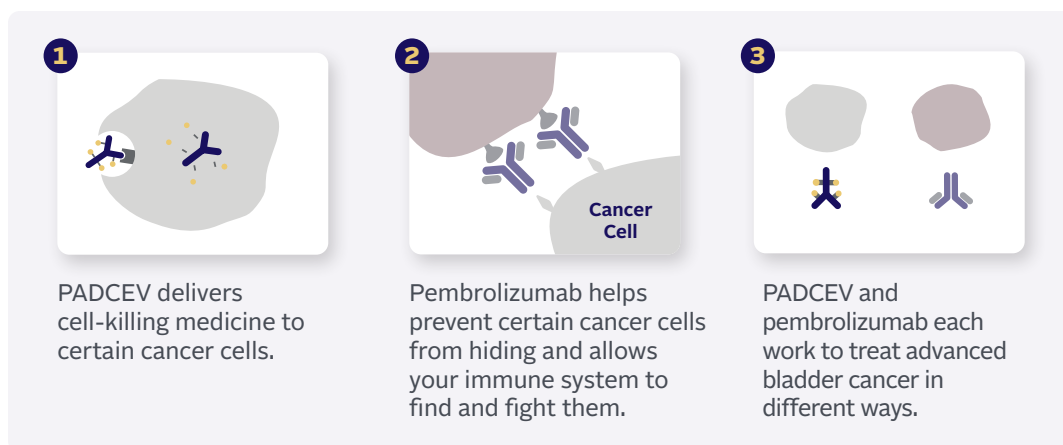
PADCEV is thought to target certain cancer cells with cell-killing medicine



This is how PADCEV was shown to work in lab studies.

PADCEV with pembrolizumab (Keytruda®)

Combines 2 therapies that treat advanced bladder cancer in different ways



Please see the pembrolizumab patient medication guide for important safety information.

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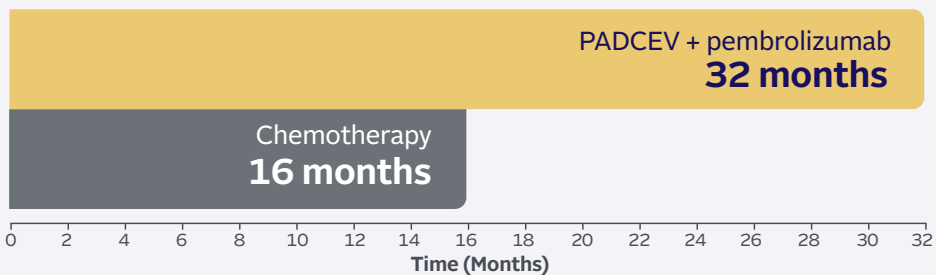
In a clinical study,


PADCEV[®] + pembrolizumab, when used as a first treatment, was shown to help some patients live twice as long as patients who were given chemotherapy

PADCEV + pembrolizumab (Keytruda[®]) was studied in people who had not been treated before for advanced bladder cancer

- This study included 886 adults, and compared the results of 442 people who received PADCEV in combination with pembrolizumab with 444 people who received cisplatin- or carboplatin-containing chemotherapy


About half of patients treated with PADCEV + pembrolizumab lived longer than 32 months
(This is called median overall survival)



 **Median overall survival:** The length of time from the start of treatment in the study that half of the people in the group were still alive.

2x
longer

The length of time about half of patients were alive without their disease getting worse was 13 months for PADCEV + pembrolizumab and 6 months for chemotherapy.*

 *This is called the **median progression-free survival**. The median progression-free survival refers to the length of time from the start of treatment in the study that half of the people in the group were still alive, and their cancer did not grow or spread.

SELECT SAFETY INFORMATION

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.

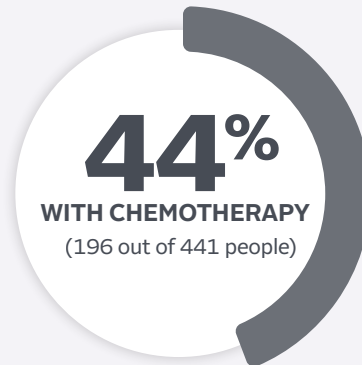
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In this clinical study,

PADCEV[®] + pembrolizumab, when used as a first treatment, was shown to help cancer shrink or disappear in more people vs chemotherapy

More people responded to treatment with PADCEV in combination with pembrolizumab (Keytruda[®])
(This is called objective response rate)



 **Objective response rate:** The percentage of people whose cancer shrinks or disappears (not detectable on tests) after treatment for a minimum time period. This does not mean the cancer has been cured.

SELECT SAFETY INFORMATION

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 (DKA), and death have happened in people with and without diabetes treated with PADCEV. Tell your healthcare provider right away if you have 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.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

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How is PADCEV® + pembrolizumab given?

Each PADCEV + pembrolizumab (Keytruda®) treatment cycle is 21 days

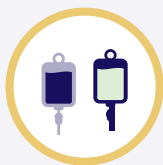
Your healthcare professional will decide how many treatment cycles you need, and may do blood tests regularly during treatment.

PADCEV is given by intravenous (IV) infusion for 30 minutes on days 1 and 8



Pembrolizumab is then given by IV infusion about 30 minutes after PADCEV on day 1

One dose of PADCEV, then one dose of pembrolizumab



DAY 1

One dose of PADCEV



DAY 8

No dose



DAYS 15-21

One week in every 21-day cycle is dose free

This timeline is only a visual representation of the dosing schedule. It is not meant to be used to track your treatment cycle. Specific days of the week may vary based on your healthcare professional's recommendation.



Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV due to side effects. It is important to play an active role and report side effects as soon as you experience them. [Download the PADCEV Discussion Guide and Symptom Tracker](#) to help track any side effects you may feel.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

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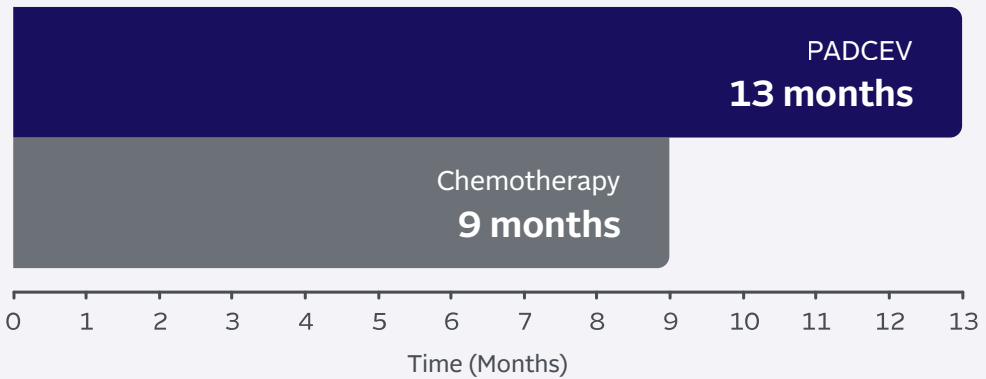
In a clinical study,


PADCEV[®], when given alone, was shown to help some people who previously received an immunotherapy medicine and cisplatin- or carboplatin-containing chemotherapy

PADCEV was shown to help some people live longer

- This study included 608 adults with advanced bladder cancer, and compared the results of 301 people who received PADCEV with the results of 307 people who received chemotherapy

**About half of patients treated with PADCEV
lived longer than 13 months**
(This is called median overall survival)



 **Median overall survival:** The length of time from the start of treatment in the study that half of the people in the group were still alive.

SELECT SAFETY INFORMATION

- **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.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

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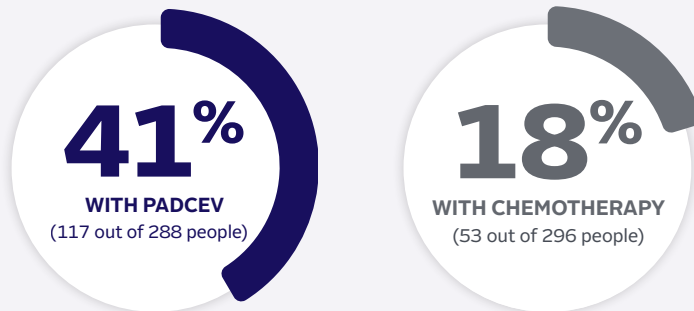
In this clinical study,


PADCEV[®], when given alone, was shown to help some people who previously received an immunotherapy medicine and cisplatin- or carboplatin-containing chemotherapy (cont'd)

More people responded to treatment with PADCEV

(This is called overall response rate)

More than twice as many people treated with PADCEV had their tumors shrink or disappear vs chemotherapy.



 **Overall response rate:** The percentage of people whose cancer shrinks or disappears (not detectable on tests) after treatment for a minimum time period. This does not mean the cancer has been cured.

SELECT SAFETY INFORMATION

- **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 have dry eyes, increased tearing, blurred vision, or any vision changes. You may use artificial tear substitutes to help prevent or treat dry eyes.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

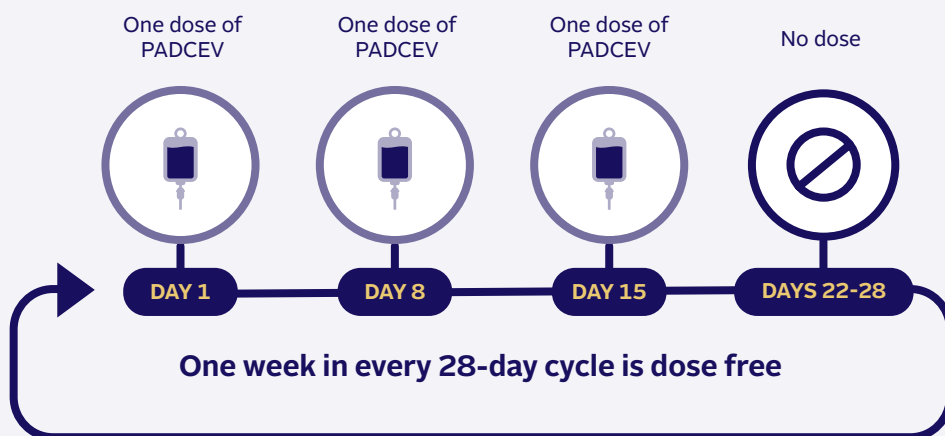
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How is PADCEV® alone given?

When given alone, each PADCEV treatment cycle is 28 days

Your healthcare professional will decide how many treatment cycles you need, and may do blood tests regularly during treatment.

PADCEV is given by IV infusion for 30 minutes on days 1, 8, and 15 of a 28-day treatment cycle



This timeline is only a visual representation of the dosing schedule. It is not meant to be used to track your treatment cycle. Specific days of the week may vary based on your healthcare professional's recommendation.



Your healthcare provider may decrease your dose of PADCEV, or temporarily or completely stop your treatment with PADCEV due to side effects. It is important to play an active role and report side effects as soon as you experience them. [Download the PADCEV Discussion Guide and Symptom Tracker](#) to help track any side effects you may feel.

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Questions for you and your caregiver to ask your healthcare team

How will this treatment affect our daily lives?

How will we know if treatment is working?

Can lifestyle changes help us manage advanced bladder cancer?

What kind of side effects might I experience and how should I report them to you?

SELECT SAFETY INFORMATION

- **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, blister, peeling skin or discomfort at the infusion site.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.



Important Safety Information

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.



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.

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Important Safety Information (cont'd)



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 (DKA), and death have happened in people with and without diabetes treated with PADCEV. Tell your healthcare provider right away if you have 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 have 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, blister, 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 have severe side effects.

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Important Safety Information (cont'd)

If your healthcare provider prescribes PADCEV® in combination with pembrolizumab for you, also read the Medication Guide that comes with pembrolizumab for important information about pembrolizumab.

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

- Changes in liver function and kidney function tests
- Rash. **See “What is the most important information I should know about PADCEV?”**
- Increased sugar (glucose) in the blood. **See “High blood sugar (hyperglycemia)”**
- Numbness or tingling in your hands or feet. **See “Nerve problems”**
- 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. **See “Eye problems”**
- 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. **See “High blood sugar (hyperglycemia)”**
- Changes in liver and kidney function tests
- Decreased white blood cell, red blood cell, and platelet counts
- Rash. **See “What is the most important information I should know about PADCEV?”**
- Tiredness
- Numbness or tingling in your hands or feet. **See “Nerve problems”**
- Decreased protein (albumin), sodium, and phosphate in the blood
- Hair loss
- Decreased appetite
- Diarrhea
- Nausea
- Itching
- Increased uric acid in the blood
- Dry eye. **See “Eye problems”**
- 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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PADCEV Support SolutionsSM is here to help

PADCEV Support SolutionsSM offers access and reimbursement support to help patients like you, who have been prescribed PADCEV[®], access their medication.

We can help evaluate your insurance coverage

PADCEV Support Solutions offers information to help you understand your insurance coverage for PADCEV. PADCEV Support Solutions will provide your healthcare professional with a summary of your insurance benefits. We can also help determine if your insurer requires a prior authorization (PA). If your insurer denies a PA request, and your healthcare professional determines that an appeal is appropriate, PADCEV Support Solutions can assist with the appeal.

PADCEV Support Solutions offers patient assistance options and financial assistance information

Copay Assistance Program

The PADCEV Copay Assistance Program is for eligible patients who have private commercial health insurance and are not insured by any federal or state healthcare program. Eligible patients pay as little as \$5 per dose and are enrolled in the program for 12 months. Under the program, eligible patients may save up to a maximum of \$25,000 per calendar year.

There are no income requirements.*

Patient Assistance Program

The PADCEV Patient Assistance Program provides PADCEV at no cost to uninsured patients who meet the program eligibility requirements.†

Financial Assistance Information

For patients who need financial assistance to help cover out-of-pocket costs, PADCEV Support Solutions can provide information about other sources of support that may be able to help.

*By enrolling in the PADCEV Copay Assistance Program ("Program"), the patient acknowledges that they currently meet the eligibility criteria and will comply with the following terms and conditions: The Program is for eligible patients with commercial prescription insurance for PADCEV[®] (enfortumab vedotin-ejfv) and is good for use only with a valid prescription for PADCEV. The Program has an annual maximum copay assistance limit of \$25,000 per calendar year. After the annual maximum on copay assistance is reached, patient will be responsible for the remaining out-of-pocket costs for PADCEV. **The Program is not valid for patients insured by any state or federal healthcare program, including, but not limited to, Medicaid, Medicare, Medigap, Department of Defense (DoD), Veterans Affairs (VA), TRICARE, Puerto Rico Government Insurance, or any state patient or pharmaceutical assistance program.** Patients who move from commercial insurance to federal or state prescription health insurance will no longer be eligible, and agree to notify the Program of any such change. This offer is not valid for cash paying patients. Patients agree not to seek reimbursement from any health insurance or third party for all or any part of the benefit received by the patient through the Program. This offer is not conditioned on any past, present, or future purchase of PADCEV. This offer is not transferrable, has no cash value, and cannot be combined with any other offer, free trial, prescription savings card, or discount. The full value of the Program benefits is intended to pass entirely to the eligible patient. The benefit available under this Program is valid only for the patient's out-of-pocket medication costs for PADCEV. The benefit is not valid for any other out-of-pocket costs such as medication administration charges or other healthcare provider services. No other individual or entity (including, without limitation, third party payers, pharmacy benefit managers, or the agents of either) is entitled to receive any benefit, discount, or other amount in connection with this Program. **This offer is not health insurance** and is only valid for patients in the 50 United States, Washington DC, and Puerto Rico. This Program is void where prohibited by law. No membership fees. Certain rules and restrictions apply. Astellas reserves the right to revoke, rescind, or amend this offer without notice for any reason (including to ensure that the offer is utilized solely for the patient's benefit).

†Subject to eligibility. Void where prohibited by law.

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



Call PADCEV Support SolutionsSM
at 1-888-402-0627 Monday-Friday,
8:30 AM to 8:00 PM ET, if you have
any questions or need assistance.



Patient Connect

PADCEV Support SolutionsSM, through the Patient Connect Program, offers additional patient and caregiver support to people like you who have been prescribed PADCEV[®]. This program helps connect you and your loved ones to educational resources and support based on your particular needs to help you manage your disease and daily life while on treatment.

When you call PADCEV Support Solutions, a trained representative will speak with you to understand the types of challenges you may be facing and will customize a search of various independent local and national organizations* that may provide support and resources right for you and your loved ones. Examples may include:



Emotional Support

- Social workers, counseling services, or online communities for you
- Emotional support for your family members and friends



Logistical Support

- Transportation and lodging assistance to get you to/from appointments
- Help with other day-to-day tasks



Informational Support

- Other education and resources about the patient's disease and treatment
- Advice and recommendations on nutrition and self-care

*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.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.



Being your own healthcare advocate

Trusting your healthcare team is important, but don't forget that you play an important role in your care. Explore the tips below to build an active partnership with your healthcare team. These can help you get the most out of your treatment plan.



Ask questions

Your healthcare team wants you to ask questions. Sometimes it helps to keep a list. If you are unclear about something your healthcare professional says, ask them to explain it again.



Keep track of symptoms and side effects

Consider keeping a journal to keep track of any side effects you experience and how you are feeling each day. You can ask your healthcare professional for a copy of the **PADCEV® Discussion Guide and Symptom Tracker** or download the tool at PADCEV.com/resources to help track this information.



Ask for help

Treatment may get difficult sometimes. Don't be afraid to reach out to friends and family. The Patient Connect Program, part of PADCEV Support SolutionsSM, may be able to help connect you and your loved ones to educational resources and support based on your particular needs.*



Talk to someone

Talk to someone, whether a healthcare professional or a loved one, about what you're going through. Consider joining a support group and looking online for additional resources. You can find additional information by visiting PADCEV.com.

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Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

 **PADCEV®**
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

Tips for caregivers

It's important to look after yourself

Try to keep these tips in mind as you support your loved one throughout their treatment.



It's OK to ask for help

As a caregiver, you may feel like you need to take care of everything, but sometimes you may need support. People may want to help you and the person you care for, but they may not know how. Speak up and ask friends and family members to help out with tasks when you need help.



Make time for yourself and other relationships

Take the time to do something you enjoy. It's also helpful to spend time with other people in your life who are important to you.



Don't forget about yourself

Being a caregiver will keep you busy. Remember to schedule appointments with your doctor to talk about ways you can stay healthy, such as eating well and getting enough sleep.

Please see Important Safety Information throughout and [read the Patient Information](#) for more information, including risk of **Serious Side Effects**.

 **PADCEV**[®]
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Injection for IV infusion 20 mg & 30 mg vials

Download more tools and resources to help support you during treatment with PADCEV®:



PADCEV Discussion Guide and Symptom Tracker

A tool to help track your symptoms and guide conversations with your healthcare team.



Dr Joe Explains: Metastatic Bladder Cancer

Tips and tools to help you take control of your experience.



A list of advocacy resources dedicated to providing help to you and your loved ones.

For more information about PADCEV, please visit [PADCEV.com](https://www.padcev.com) or call 1-888-4PADCEV (1-888-472-3238)

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

 **PADCEV**[®]
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

PATIENT INFORMATION

PADCEV® (PAD-sev)
(enfortumab vedotin-ejfv)
for injection

If your healthcare provider prescribes PADCEV in combination with pembrolizumab for you, also read the Medication Guide that comes with pembrolizumab for important information about pembrolizumab.

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.

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 with pembrolizumab, **or**
- PADCEV may be used alone if you:
 - have received an immunotherapy medicine **and** chemotherapy that contains platinum, **or**
 - are not able to receive a chemotherapy that contains the medicine cisplatin **and** you have received 1 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.

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.
- 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.

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.
- PADCEV is given over periods of time called “cycles”.
- If you receive PADCEV with pembrolizumab,
 - Each cycle is 21 days.
 - You will receive PADCEV on days 1 and 8 of every cycle.
- If you receive PADCEV alone,
 - 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:

- 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 (DKA), and death have happened in people with and without diabetes, treated with PADCEV. Tell your healthcare provider right away if you have 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 also 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 have 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, blister, 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 have severe side effects.

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

- changes in liver function and kidney function tests
- rash. See “What is the most important information I should know about PADCEV?”
- increased sugar (glucose) in the blood. See “High blood sugar (hyperglycemia)” above.
- numbness or tingling in your hands or feet. See “Nerve problems” above.
- 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. See “Eye problems” above.
- 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. See “High blood sugar (hyperglycemia)” above.
- changes in liver and kidney function tests
- decreased white blood cell, red blood cell, and platelet counts
- rash. See “What is the most important information I should know about PADCEV?”
- tiredness
- numbness or tingling in your hands or feet. See “Nerve problems” above.
- decreased protein (albumin), sodium, and phosphate in the blood
- hair loss
- decreased appetite
- diarrhea
- nausea
- itching
- increased uric acid in the blood
- dry eye. See “Eye problems” above.
- 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 of the possible side effects of PADCEV.

Call your doctor 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 PADCEV.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about PADCEV that is written for healthcare professionals.

What are the ingredients in PADCEV?

Active ingredient: enfortumab vedotin-ejfv

Inactive ingredients: histidine, histidine hydrochloride monohydrate, polysorbate 20, and trehalose dihydrate.

Manufactured and Marketed by: Astellas Pharma US, Inc., Northbrook, Illinois 60062

Distributed and Marketed by: Seagen Inc., Bothell, WA 98021

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For more information, go to www.padcev.com or call 1-888-4-PADCEV

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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