

# PADCEV® Discussion Guide and Symptom Tracker

Bring this guide to your next appointment to:

- Help you have more detailed conversations with your healthcare team
- Help you keep your healthcare team aware of how you are feeling while taking PADCEV



## Office contacts:

Doctor: \_\_\_\_\_

Nurse: \_\_\_\_\_

Location: \_\_\_\_\_

Phone: \_\_\_\_\_

## Appointment reminders:

Date: \_\_\_\_\_

Time: \_\_\_\_\_

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## 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.

## SELECT 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 during treatment 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)
- blistering or peeling of the skin
- fever or flu-like symptoms
- rash or itching that continues to get worse
- painful sores or ulcers in mouth or nose, throat, or genital area
- swollen lymph nodes

**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

## IMPORTANT SAFETY INFORMATION

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

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- 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?

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- 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

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



**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.
- **High Blood Sugar (hyperglycemia).** You can develop high blood sugar during treatment with PADCEV. High blood sugar, a serious condition called diabetic ketoacidosis (DKA), and death have happened in people with and without diabetes who were 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.



**PADCEV**

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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. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.



• **Peripheral neuropathy.** You may develop nerve problems called peripheral neuropathy during treatment with PADCEV. 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.** You can develop certain eye problems during treatment with PADCEV. Tell your healthcare provider right away if you have dry eyes, 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, or discomfort at the infusion site.

### 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
- 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

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

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.



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](http://www.fda.gov/medwatch).

## Discussing PADCEV® with your healthcare team

Starting a new treatment can come with questions. Use the sample questions below to start the PADCEV conversation with your healthcare team and help you get the information you need.

How is PADCEV different from other treatments I have tried?

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

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How will I know if PADCEV is working for me?

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How will PADCEV affect my daily life?

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### Caregiver corner



#### ASK FOR HELP

Treatment may get difficult sometimes. The Patient Connect Program, part of PADCEV Support Solutions<sup>SM</sup>, may be able to provide resources to help.<sup>1</sup> See the back cover for PADCEV Support Solutions contact information.

Is there someone I can talk to for emotional support, or are there support groups I can join?

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Is there a website or other materials where I can learn more about PADCEV, metastatic bladder cancer, and supporting my loved one through treatment?

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Is there financial support that you can connect us with?

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

<sup>1</sup>Support is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas or Seagen. Availability of support and eligibility requirements are determined by these organizations.

## Discussing possible PADCEV® side effects with your healthcare team

Use the below sample questions to discuss the possible side effects of treatment with PADCEV.

What are the possible side effects I may experience while using PADCEV?

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When should I call the doctor if I experience a side effect?

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

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Use this space to write any additional notes or questions you may have.

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### The most common side effects of PADCEV

Let your healthcare team know right away if you think you might be experiencing any of the side effects listed below or any other symptoms.

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

These are not all of the possible side effects of PADCEV. For more information, see page 2 and talk to your healthcare team.



Visit [PADCEV.com](https://www.padcev.com) for more information about your treatment and for additional resources to download or print.

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

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# Tracking your symptoms

It's important to keep your healthcare team aware of how you're feeling. The earlier you let your healthcare team know, the more they'll be able to help you. Use the table below to track any symptoms you might be experiencing while taking PADCEV®.

For each day you experience a symptom, write the number that represents the degree of the symptom:

 **1**  
Hardly noticeable

 **2**  
Noticeable, but can still do usual activities

 **3**  
Uncomfortable, unable to do some activities

 **4**  
Very uncomfortable, hard to do any activities

 **5**  
Unbearable, unable to do any activities

CYCLE:	Week of:							Week of:							Week of:							Week of:						
List the symptoms that you are experiencing below	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S
Example: <i>Feeling tired</i>	1		2	2	3		1	1	1	2	1		2	1	2	2	1			1	1		1	1	2		1	

 **REMINDER:** PADCEV is given on days 1, 8, and 15 of a 28-day treatment cycle.

 **NOTE:** Print additional copies of this page to continue tracking your symptoms each week up until your next appointment.

 If you experience certain side effects, your healthcare team may decrease your dose or stop your treatment with PADCEV for a period of time (temporarily) until symptoms improve or resolve completely.

Call your healthcare team right away if you experience side effects. You may report side effects to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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## Tracking your symptoms (cont'd)

CYCLE:	Week of:							Week of:							Week of:							Week of:						
List the symptoms that you are experiencing below	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S

CYCLE:	Week of:							Week of:							Week of:							Week of:						
List the symptoms that you are experiencing below	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S

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## **PADCEV Support Solutions<sup>SM</sup> 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.<sup>1</sup>



**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<sup>®</sup>, and to download additional copies of this Discussion Guide and Symptom Tracker, please visit [PADCEV.com](https://www.padcev.com).**

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Seagen and the Seagen logo are registered trademarks of Seagen Inc.

PADCEV Support Solutions<sup>SM</sup>, a component of Astellas Pharma Support Solutions<sup>SM</sup>, is a service mark of Astellas Pharma US, Inc.

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## PATIENT INFORMATION

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

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- 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.

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- 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).** You can develop high blood sugar during treatment with PADCEV. 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. Tell your healthcare provider right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough.
- **Peripheral neuropathy.** You may develop nerve problems called peripheral neuropathy during treatment with PADCEV. Tell your healthcare provider right away if you get new or worsening numbness or tingling in your hands or feet or muscle weakness.
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### The most common side effects of PADCEV include:

- |   |  |   |
|---|--|---|
| • skin rash   | • hair loss  | • itching   |
| • changes in liver and kidney function tests                      | • decreased appetite   | • change in sense of taste                                    |
| • increased sugar (glucose) in the blood                          | • diarrhea   | • increased uric acid in the blood                            |
| • tiredness   | • decreased sodium, phosphate and protein (albumin) in the blood | • increased lipase (a blood test done to check your pancreas) |
| • numbness or tingling in your hands or feet, or muscle weakness  | • nausea   | • decreased weight  |
| • decreased white blood cell, red blood cell, and platelet counts |  | • 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.

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 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. 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.

### What are the ingredients in PADCEV?

**Active ingredient:** enfortumab vedotin-ejfv

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