Muscle-Invasive Bladder Cancer (MIBC)*

Multiply Your Moments

Adults with MIBC who received PADCEV® + pembrolizumab (Keytruda®) before and after bladder removal surgery:

- **Experienced fewer cancer-related events†**
- **Were more likely to be alive**

compared to those who received chemotherapy before bladder removal surgery or bladder removal surgery alone based on two clinical studies.‡

†Events include not being able to get surgery due to cancer, cancer remaining after surgery, cancer getting worse or coming back, or death.

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

‡Based on two clinical studies. In a study of 808 adults able to receive chemotherapy containing the medicine cisplatin (cisplatin-based chemotherapy), 79% of people treated with PADCEV + pembrolizumab, given before and after surgery, did not experience cancer-related events, compared with 64% of people who received chemotherapy before surgery. 83% of people who received PADCEV + pembrolizumab before and after surgery were still alive at the time the clinical study was evaluated, compared with 75% of people who received chemotherapy before surgery. In a study of 344 adults not able to receive cisplatin-based chemotherapy, 72% of people treated with PADCEV + pembrolizumab, given before and after surgery, did not experience cancer-related events, compared with 45% of people who received surgery alone. 78% of people who received PADCEV + pembrolizumab before and after surgery were still alive at the time the clinical study was evaluated, compared with 61% of people who received surgery alone.

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.

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

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

This guide can help you get started on PADCEV® + pembrolizumab

Starting cancer treatment can feel overwhelming, but learning more about your disease and the options available to you can help you feel more in control.

PADCEV (PAD-sev) + pembrolizumab (Keytruda®), or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™), given before and after surgery, is a treatment option for adults with muscle-invasive bladder cancer (MIBC).

Clinical study results show how this treatment regimen worked in two different groups of people:

PEOPLE **ABLE TO RECEIVE** CISPLATIN-BASED CHEMOTHERAPY

Pg 6

PEOPLE **NOT ABLE TO RECEIVE** CISPLATIN-BASED CHEMOTHERAPY

Pg 13

If your doctor thinks that PADCEV + pembrolizumab treatment, given before and after surgery, is an appropriate option, then this combination may help you live longer and give you more time without experiencing cancer-related events than chemotherapy before surgery or surgery alone. Cancer-related events included not being able to get surgery due to cancer, cancer remaining after surgery, cancer getting worse or coming back, or death.

What is cisplatin?

Cisplatin is a type of chemotherapy that has traditionally been used as a treatment for MIBC.

Some people can receive cisplatin (cisplatin-eligible) and others cannot (cisplatin-ineligible). Factors such as kidney and liver function, hearing, nerve health, and ability to perform daily activities may affect whether cisplatin is a recommended option. Because doctors have historically chosen MIBC treatment based on cisplatin-eligibility, PADCEV + pembrolizumab was studied in both groups of people.

Ask your healthcare team which group you fit into, so you can focus on the PADCEV study results that are most relevant to you.

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.

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What you will find in this guide

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What should I know about my disease?

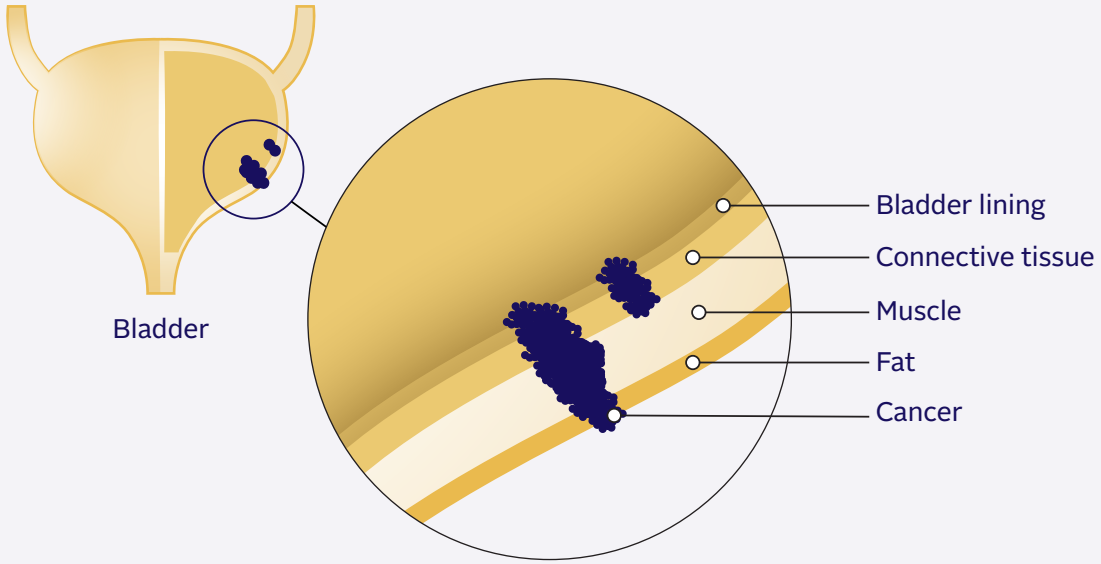
If you are reading this guide, it is likely that you or someone you care for has been diagnosed with MIBC. What does that mean?

Bladder cancer typically begins in the cells that line the bladder. In MIBC, the cancer grows into, and sometimes through, the bladder muscle.

MIBC can often require aggressive treatment to help stop the disease from getting worse or coming back. For people with MIBC, surgery is performed with the goal of curing the disease. Treatments given before or after surgery are intended to support MIBC care.

Many people with MIBC can benefit from working closely with their healthcare team and receiving treatment. If you are diagnosed with MIBC, remember that support is available, and you are not alone.

MIBC IS CANCER THAT HAS GROWN INTO AND SOMETIMES THROUGH THE BLADDER MUSCLE



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.

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

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Why is treatment given before and after bladder removal as part of a 3-phase plan?

For people with MIBC, receiving treatment before and after surgery may help to treat the cancer effectively and may help prevent it from coming back.

This approach begins with treatment before surgery, which is intended to help shrink the cancer and make it easier to remove. After surgery, cancer cells can still be present. Treatment after surgery is intended to help target remaining cancer cells. Treatment may also target healthy cells, which may result in side effects.

That is why understanding all 3 phases and combining treatment before and after surgery are important parts of your overall care plan.

TREATMENT IS GIVEN BEFORE AND AFTER SURGERY

1

PHASE 1:

BEFORE SURGERY (NEOADJUVANT TREATMENT)

Treatment intended to help shrink the tumor

2

PHASE 2:

BLADDER REMOVAL SURGERY

An operation that may lower the risk of the disease getting worse or returning

3

PHASE 3:

AFTER SURGERY (ADJUVANT TREATMENT)

Treatment intended to help target any remaining cancer cells

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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.

A CLINICAL STUDY FOR ADULTS WITH MIBC WHO WERE ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

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HOW PADCEV® + PEMBROLIZUMAB WERE STUDIED IN ADULTS WITH MIBC WHO WERE ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

A clinical study of PADCEV + pembrolizumab given before and after surgery vs chemotherapy given before surgery

Study Design

THE STUDY COMPARED 2 GROUPS OF ADULTS WITH MIBC WHO WERE ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY*:

405		403
people who received PADCEV + pembrolizumab (Keytruda®) before and after surgery	VS	people who received chemotherapy before surgery

BEFORE SURGERY

1. **4 CYCLES *(12 weeks)*** of PADCEV and pembrolizumab together — **4 CYCLES *(12 weeks)*** of chemotherapy

2. **BLADDER REMOVAL SURGERY**

AFTER SURGERY

3. **5 CYCLES *(15 weeks)*** of PADCEV and pembrolizumab together followed by **8 CYCLES *(24 weeks)*** of pembrolizumab alone — no treatment†

*Treatment continued until it was completed, the cancer got worse, surgery did not take place, the cancer returned, or side effects became too severe.

†Some people received immunotherapy when medically appropriate and available in their country.

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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BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC **WHO WERE ABLE TO RECEIVE** CISPLATIN-BASED CHEMOTHERAPY

PADCEV® + pembrolizumab given before and after surgery helped more people stay free from a cancer-related event

Event-free survival

More people did not experience a cancer-related event at the time the study results were reviewed:

PADCEV + pembrolizumab (Keytruda®) before and after surgery

79%

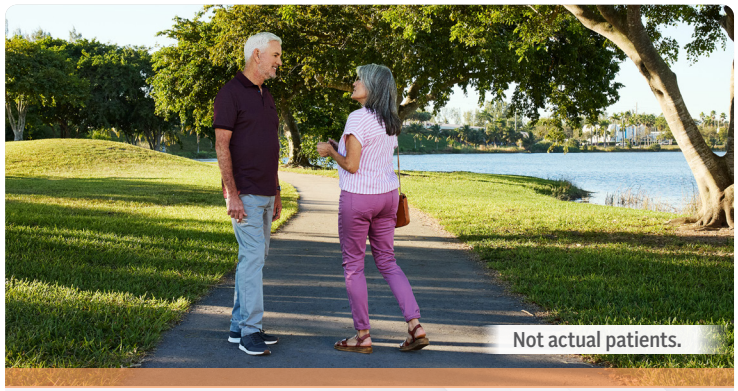
318 OUT OF **405** PEOPLE
stayed free from a cancer-related event

VS

Chemotherapy before surgery

64%

257 OUT OF **403** PEOPLE
stayed free from a cancer-related event



A **cancer-related event** included not being able to get surgery due to cancer, cancer remaining after surgery, cancer getting worse or coming back, or death.

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, 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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BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC **WHO WERE ABLE TO RECEIVE** CISPLATIN-BASED CHEMOTHERAPY

More people were still living with PADCEV® + pembrolizumab given before and after surgery

Overall survival

More people were still alive at the time the clinical study was evaluated

PADCEV + pembrolizumab (Keytruda®) before and after surgery

83% — 336 out of 405 people were still alive

vs

Chemotherapy before surgery

75% — 304 out of 403 people were still alive

This is called **overall survival**. It measures the amount of people in a study who are still alive for a given period of time after they started treatment.

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 here for more information, including risk of Serious Side Effects.

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BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC **WHO WERE ABLE TO RECEIVE** CISPLATIN-BASED CHEMOTHERAPY

More people had no detectable cancer cells at the the time of surgery when treated with PADCEV® + pembrolizumab

Pathological complete response

Doctors found no trace of bladder cancer in tissue removed during surgery in:

56% **of people treated with PADCEV + pembrolizumab**
226 out of 405 people

VS

33% **of people treated with chemotherapy**
131 out of 403 people

This does not mean the cancer was cured.

This is called **pathological complete response**. It means that after treatment, when doctors examine the tissue removed during surgery or biopsy, no cancer cells are seen under the microscope.

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.

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

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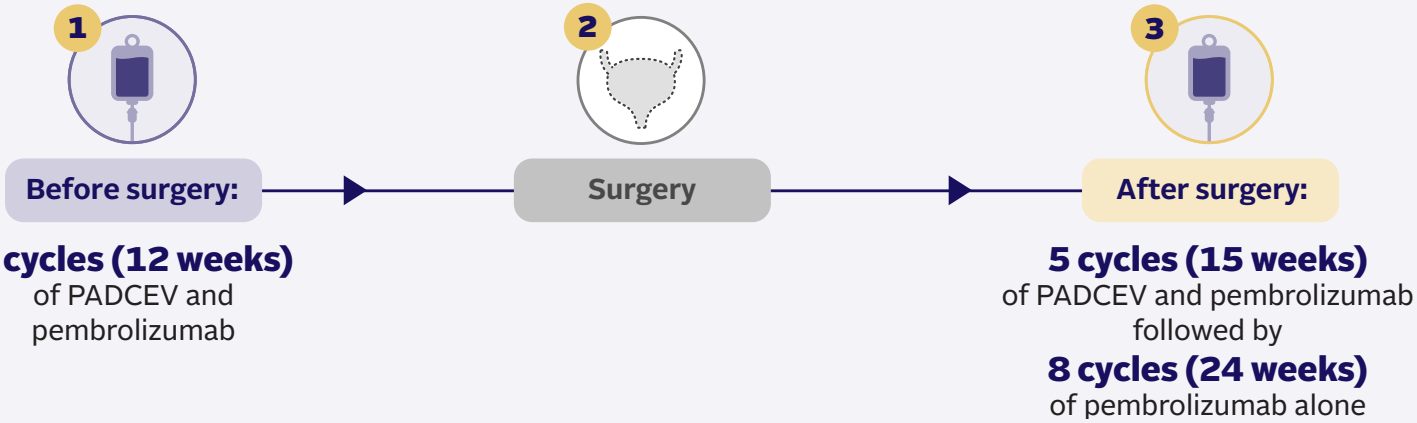
FOR ADULTS WITH MIBC WHO ARE ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

What to expect with your PADCEV® + pembrolizumab treatment plan

Your PADCEV + pembrolizumab (Keytruda®) treatment plan includes 3 phases:

1. Treatment before surgery
2. Surgery
3. Treatment after surgery

People in the study received PADCEV + pembrolizumab both before and after surgery. Take a look below to see how many treatment cycles are planned for each phase:



You will not need to keep track of this on your own. Your healthcare team will work together to help plan your treatment cycles and surgery timing.

PADCEV is given by your healthcare professional as an intravenous (IV) infusion. You may receive pembrolizumab as an IV infusion or a subcutaneous injection. Your doctor may also adjust the timing of your treatment cycles based on what is right for you. Talk to your doctor about what your dosing schedule may look like.

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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.

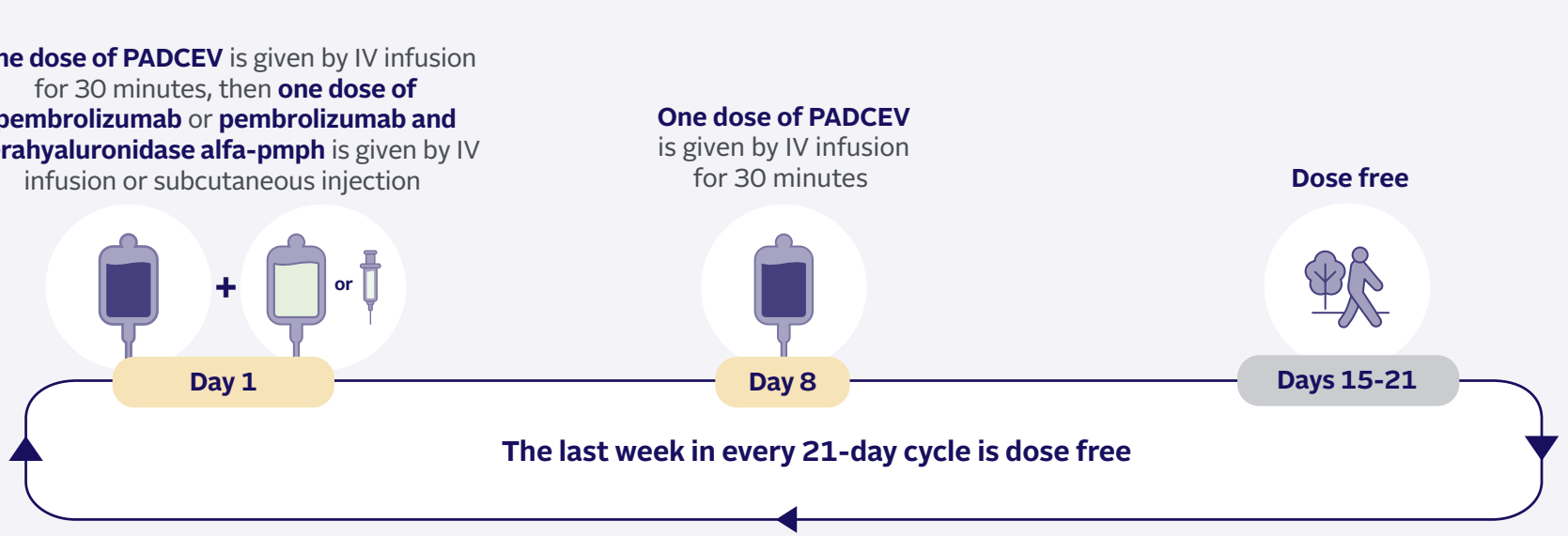
FOR ADULTS WITH MIBC WHO ARE ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

What to expect with the PADCEV® + pembrolizumab treatment schedule

Dosing

When you receive PADCEV with pembrolizumab (Keytruda®) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™), each treatment cycle is 21 days

During treatment, your doctor may regularly do blood tests.



For example, if you receive your first dose of PADCEV with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph on a Monday, you would have another dose of PADCEV the following Monday, and then the next Monday would be 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.

Talk to your doctor about what your dosing schedule may look like.

For additional dosing information, see the Medication Guides for pembrolizumab and for pembrolizumab and berahyaluronidase alfa-pmph.

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A CLINICAL STUDY FOR ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

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HOW PADCEV® + PEMBROLIZUMAB WERE STUDIED IN ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

A clinical study of PADCEV + pembrolizumab given before and after surgery vs surgery alone

Study Design

THE STUDY COMPARED 2 GROUPS OF ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY*:

170	VS	174
people who received PADCEV + pembrolizumab (Keytruda®) before and after surgery		people had surgery alone

BEFORE SURGERY

1

3 CYCLES ***(9 weeks)*** of PADCEV and pembrolizumab together	no treatment

2

BLADDER REMOVAL SURGERY

AFTER SURGERY

3

6 CYCLES ***(18 weeks)*** of PADCEV and pembrolizumab together followed by **8 CYCLES** ***(24 weeks)*** of pembrolizumab alone	no treatment†

*Treatment continued until it was completed, the cancer got worse, surgery did not take place, the cancer returned, or side effects became too severe.

†Some people received immunotherapy when medically appropriate and available in their country.

SELECT SAFETY INFORMATION

- **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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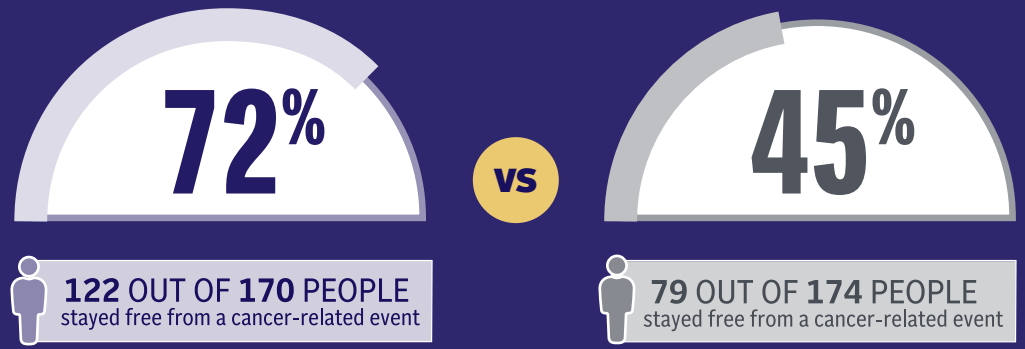
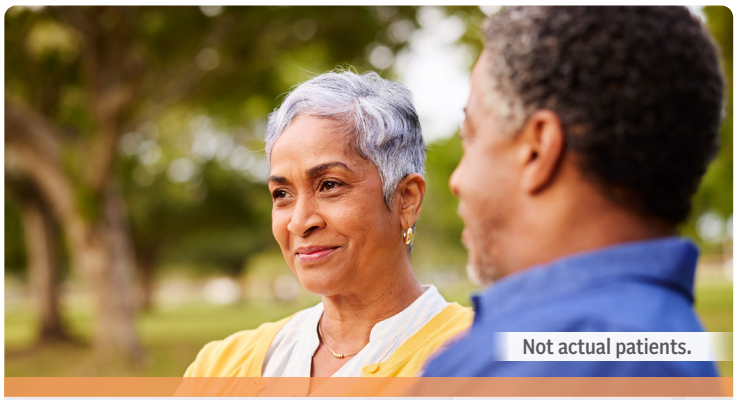
BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

PADCEV® + pembrolizumab given before and after surgery helped more people stay free from a cancer-related event

Event-free survival

More people did not experience a cancer-related event at the time the study results were reviewed:





A **cancer-related event** included not being able to get surgery due to cancer, cancer remaining after surgery, cancer getting worse or coming back, or death.

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, blistering, peeling skin or discomfort at the infusion site.

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BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

More people were still living with PADCEV® + pembrolizumab given before and after surgery

Overall survival

More people were still alive at the time the clinical study was evaluated

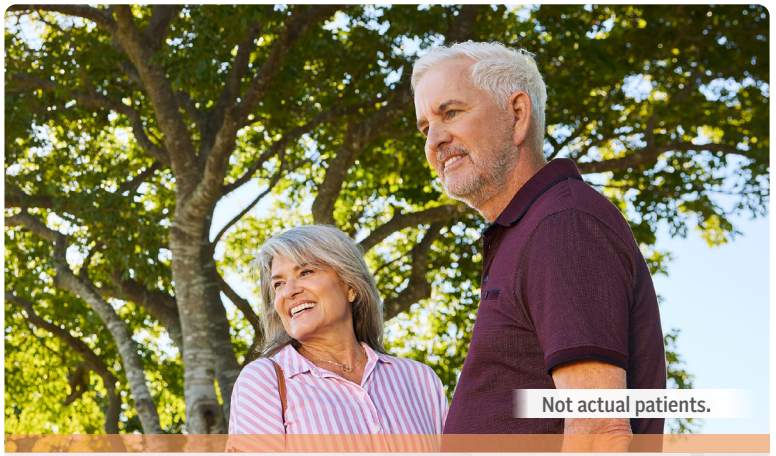
PADCEV + pembrolizumab (Keytruda®) before and after surgery

78% — 132 out of 170 people were still alive

vs

Surgery alone

61% — 106 out of 174 people were still alive



This is called **overall survival**. It measures the amount of people in a study who are still alive for a given period of time after they started treatment.

SELECT SAFETY INFORMATION

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- 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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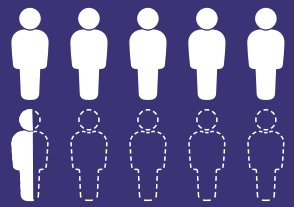
BASED ON A CLINICAL STUDY FOR ADULTS WITH MIBC WHO WERE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

More people had no detectable cancer cells at the time of surgery when treated with PADCEV® + pembrolizumab

Pathological complete response

57% of people treated with PADCEV + pembrolizumab (Keytruda®) had **NO TRACE OF BLADDER CANCER** IN TISSUE REMOVED DURING SURGERY*



*Compared to 9% with surgery alone.
This does not mean the cancer was cured.

This is called a **pathological complete response**. It means that after treatment, when doctors examine the tissue removed during surgery or biopsy, no cancer cells are seen under the microscope.

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.

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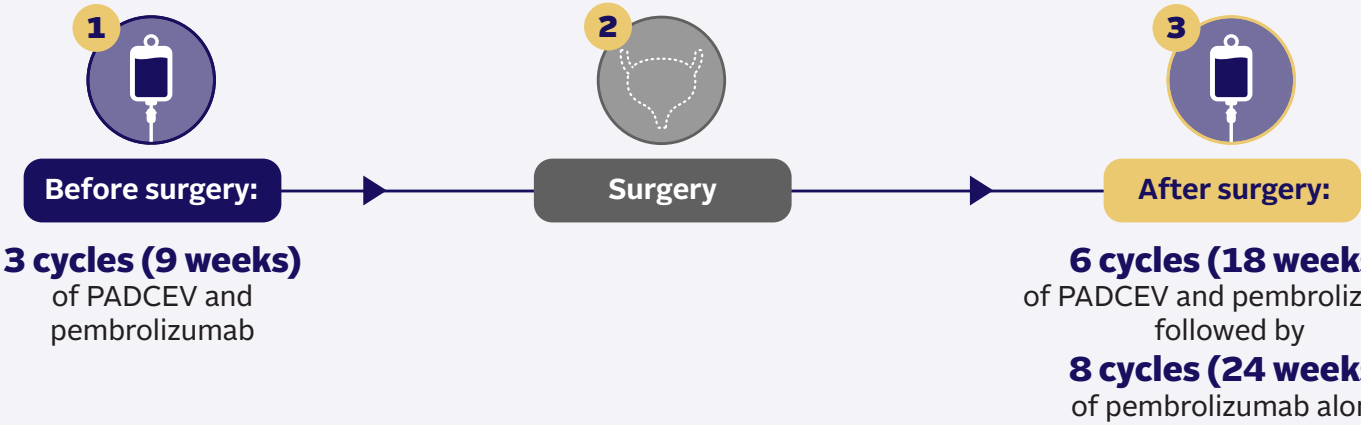
FOR ADULTS WITH MIBC WHO ARE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

What to expect with your PADCEV® + pembrolizumab treatment plan

Your PADCEV + pembrolizumab (Keytruda®) treatment plan includes 3 phases:

1. Treatment before surgery
2. Surgery
3. Treatment after surgery

People in the study received PADCEV + pembrolizumab both before and after surgery. Take a look below to see how many treatment cycles are planned for each phase:



You will not need to keep track of this on your own. Your healthcare team will work together to help plan your treatment cycles and surgery timing.

PADCEV is given by your healthcare professional as an IV infusion. You may receive pembrolizumab as an IV infusion or a subcutaneous injection. Your doctor may also adjust the timing of your treatment cycles based on what is right for you. Talk to your doctor about what your dosing schedule may look like.

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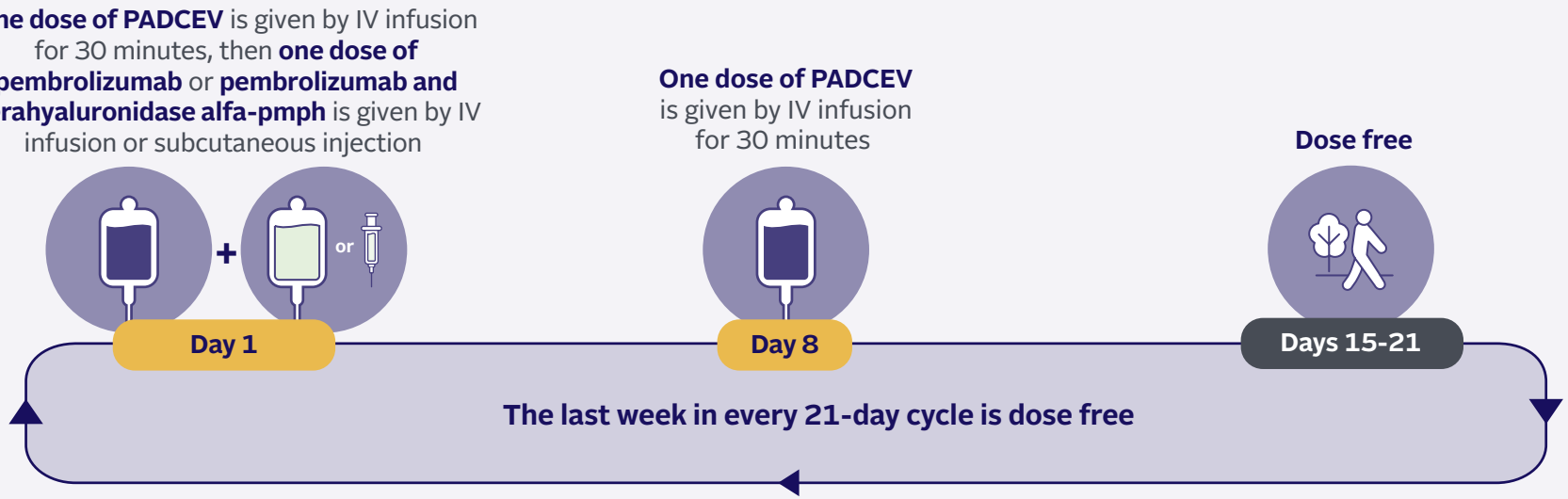
Please see Important Safety Information throughout and read the Patient Information here for more information, including risk of Serious Side Effects.

FOR ADULTS WITH MIBC WHO ARE NOT ABLE TO RECEIVE CISPLATIN-BASED CHEMOTHERAPY

What to expect with the PADCEV® + pembrolizumab treatment schedule

When you receive PADCEV with pembrolizumab (Keytruda®) or pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex™), each treatment cycle is 21 days

During treatment, your doctor may regularly do blood tests.



For example, if you receive your first dose of PADCEV with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph on a Monday, you would have another dose of PADCEV the following Monday, and then the next Monday would be dose free.

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Talk to your doctor about what your dosing schedule may look like.

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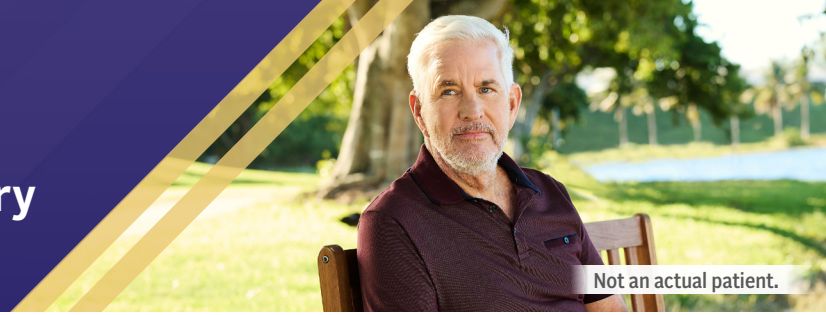
How side effects may be managed during treatment with PADCEV® + pembrolizumab given before and after surgery



To help manage your side effects with PADCEV,

Your doctor may:

- **Decrease** your dose
- **Temporarily pause** your treatment
- **Completely stop** your treatment

Side effects may occur at any time during treatment with PADCEV, **but reporting them early may help manage them more appropriately**.

That is why it is important for you to take an active role in your treatment, and **alert your care team as soon as you experience any side effects**.

In clinical studies for PADCEV, people who experienced side effects may have had a dose reduction, dose hold, or discontinuation to help manage their side effects.

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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.

Side effects to watch for when taking PADCEV® in combination with pembrolizumab

PADCEV may cause serious side effects, including:

- Skin reactions
- High blood sugar (hyperglycemia)
- Lung problems
- Nerve problems
- Eye problems
- Leakage of PADCEV out of your vein into the tissues around your infusion site (extravasation)

The following are the most common side effects of PADCEV when used in combination with pembrolizumab (Keytruda®):

- 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

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

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

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PADCEV® is different from traditional chemotherapy

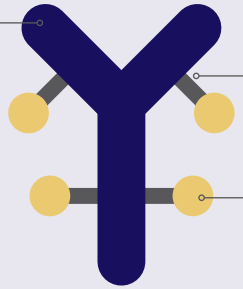
PADCEV is used to treat some types of bladder cancer

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

- PADCEV is **different from chemotherapy or immunotherapy**
- 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 20 and 21** 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

What is an antibody?

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

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

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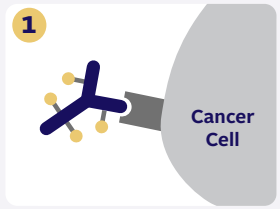
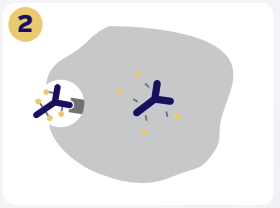
How PADCEV® is thought to work

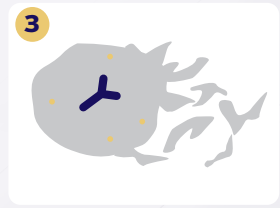
PADCEV is thought to target certain cancer cells with cell-killing medicine



PADCEV attaches to the surface of the cancer cell.



PADCEV enters the cancer cell and releases cell-killing medicine.

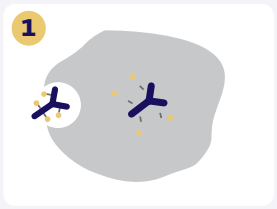


The medicine works to damage and kill the cancer cell.

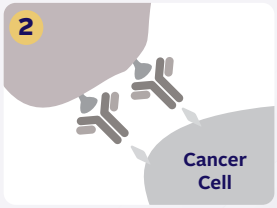
This is how PADCEV was shown to work in lab studies.

PADCEV with pembrolizumab (Keytruda®)

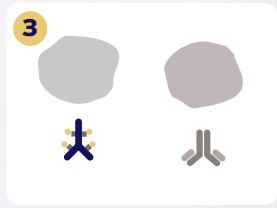
Combines 2 therapies that treat bladder cancer in different ways



PADCEV delivers cell-killing medicine to certain cancer cells.



Pembrolizumab helps prevent certain cancer cells from hiding and allows your immune system to find and fight them.



PADCEV and pembrolizumab each work to treat bladder cancer in different ways.

Please see the pembrolizumab patient Medication Guide for important safety information.

PADCEV + pembrolizumab works with surgery in a 3-phase treatment plan—to help shrink cancer before surgery and target any cancer cells that may remain afterward.

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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, 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.
- **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.

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Important Safety Information (cont'd)

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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PADCEV Support Solutions® is here to help

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SUPPORT SOLUTIONS

PADCEV Support Solutions 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 process.*

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, including, but not limited to, Medicare, Medicaid, TRICARE, or Veterans Affairs (VA).

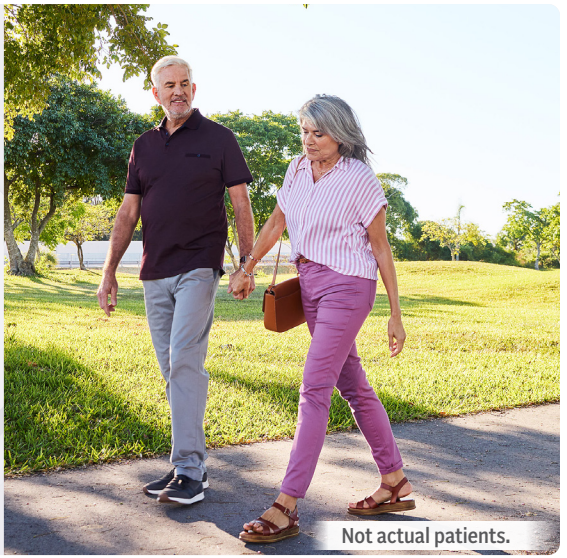
Eligible patients may pay as little as $5 per dose and will be enrolled in the program for a 12-month period. Under the Program, eligible patients have an annual maximum copay assistance limit of $25,000 per calendar year. There are no income requirements.†

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.


Not actual patients.

*The healthcare provider remains responsible for providing all clinical information.

†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 transferable, 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 criteria. Terms and conditions apply. Void where prohibited by law.

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PADCEV Support Solutions® is here to help (cont'd)

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

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SUPPORT® SOLUTIONS

Patient Connect

PADCEV Support Solutions, 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 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 your disease and treatment
- Information 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.

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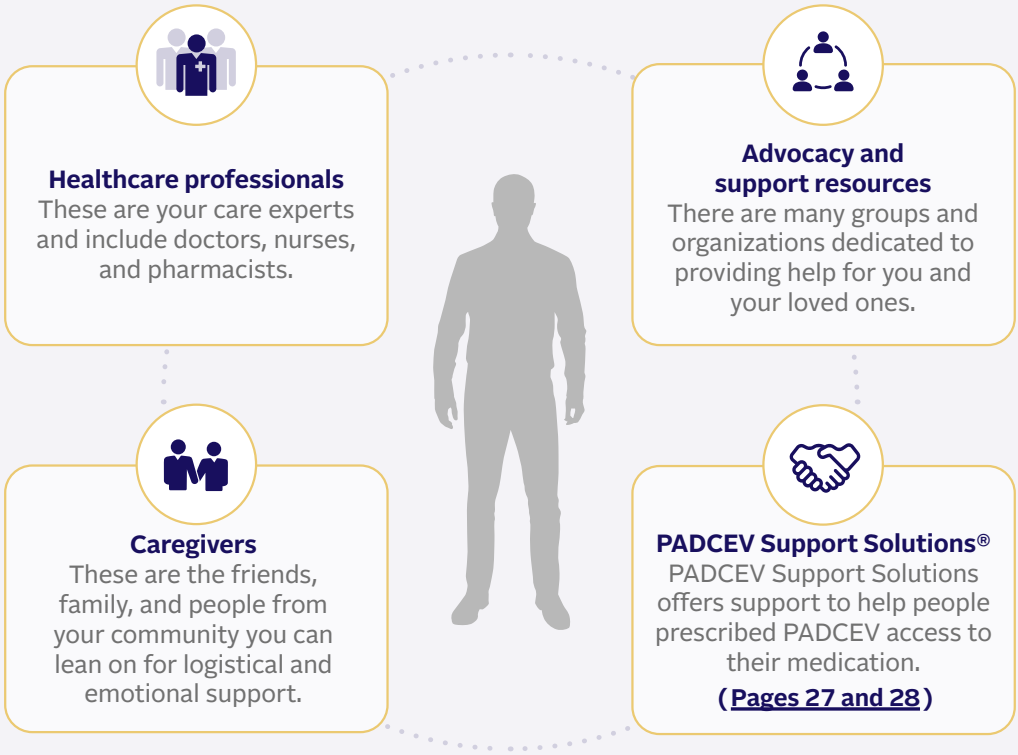
How to play an active role in your treatment with PADCEV®

Playing an active role in your treatment is important

- Make sure to keep your appointments, and stay on schedule
- Talk to your healthcare team about any scheduling concerns
- Reach out to your healthcare team right away if you are feeling unwell or notice any side effects
- Use a journal to keep a daily track of possible side effects or changes you may experience

Your care team is here to help and support you as you receive treatment. Never hesitate to reach out to them when you need something or notice anything different. The sooner you communicate with them, the better they can help you.



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Questions for you and your caregiver to ask your healthcare team

How will treatment affect my ability to work or care for my family?

How will I know if the treatment is working?

Why is treatment recommended before and after surgery?

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

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.

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

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If you are caring for a loved one, look after yourself too

Caring for a loved one who is undergoing the 3-phase treatment plan for PADCEV® + pembrolizumab (Keytruda®) can be challenging. Staying strong and motivated is key to optimizing treatment for your loved one.

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

It is 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 it.

Make time for yourself and other relationships

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

Your health matters too

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

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For more information about PADCEV®, please visit PADCEV.com/mibc or call 1-888-4PADCEV (1-888-472-3238).

Visit PADCEV.com/mibc and find tools that can help support you during your treatment with PADCEV.

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