

# HCP Portal User Guide



## **BOXED WARNING: SERIOUS SKIN REACTIONS**

- **PADCEV can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurred predominantly during the first cycle of treatment, but may occur later.**
- **Closely monitor patients for skin reactions.**
- **Immediately withhold PADCEV and consider referral for specialized care for suspected SJS or TEN or severe skin reactions.**
- **Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.**

## **Indication**

PADCEV®, in combination with pembrolizumab, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC).

PADCEV, as a single agent, is indicated for the treatment of adult patients with locally advanced or mUC who:

- have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or
- are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.

**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**

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PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

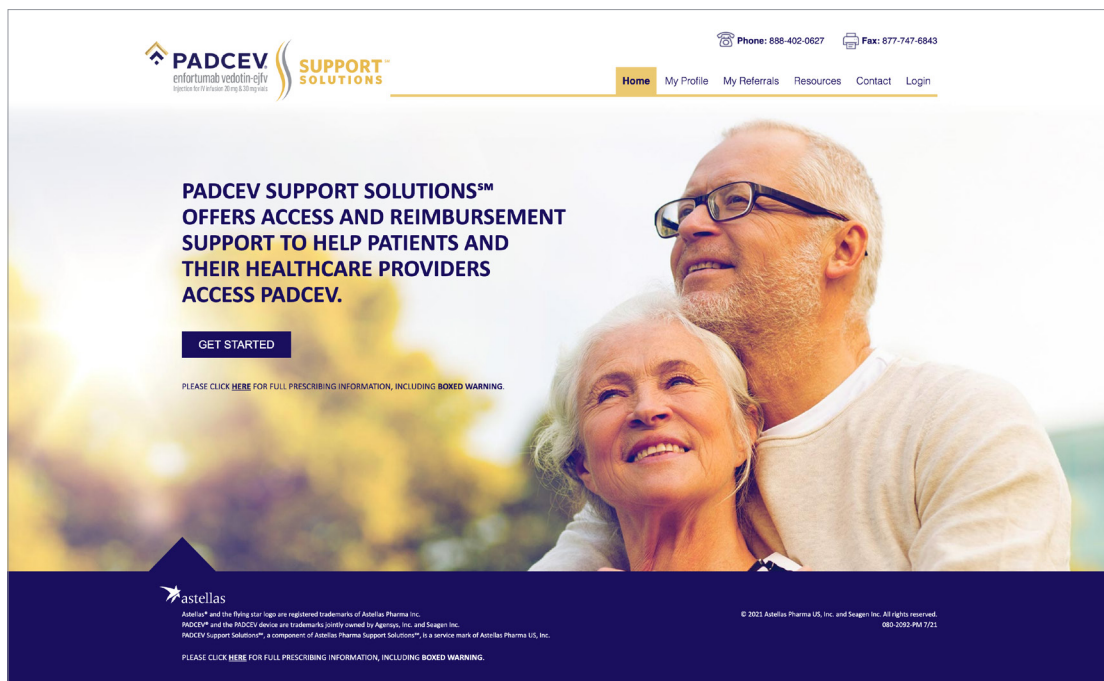
# OVERVIEW

The PADCEV Support Solutions prescriber portal is an online healthcare provider tool that allows Healthcare Providers to:

- Enter new referral requests
- Obtain status updates on current referral requests
- Upload additional documentation for referral requests

## LOGGING ON

To access the PADCEV® prescriber portal website, go to: <https://padcev.aspnprograms.com>



**First-Time Users:** Click **Get Started** to begin the registration process. Continue to Verify Page of this document.

**Returning Users:** Click the **Login** button at the top right of the page. In the User Login modal that pops up, enter your User Name and Password, then click **Login**. Continue to page 6 of this document.

The image shows a "User Login" modal form. It has a dark blue header with the text "User Login" and a close button (X). Below the header, there are two input fields: "Username" and "Password". The "Password" field has a "Login" button next to it. Below the input fields, there is a link: "Forgot username or password?". At the bottom of the modal, there is a link: "New User? Click here to register now >>".

**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**

# LOGGING ON CONT.

## New User Registration

Enter the office information: Prescriber Name or Practice Name, Address, Phone, Fax, User Name, Email and Password.

The screenshot shows the PADCEV Support Solutions registration page. At the top, there is a header with the PADCEV logo (enfortumab vedotin-ejfv injection for IV infusion 20 mg & 50 mg Vials) and the SUPPORT SOLUTIONS logo. To the right of the header, there are contact numbers: Phone: 888-402-0627 and Fax: 877-747-6843. Below the header is a navigation bar with links: Home, My Profile, My Referrals, Resources, Contact, and Login. The main content area is divided into two sections: 'Registration' and 'User Agreements'. The 'Registration' section contains a 'Prescriber/Practice Registration' form with fields for: \*Prescriber/Practice Name, \*Address 1, Address 2, \*Zip, \*City, \*State (dropdown), \*Phone, Fax, \*User Name, \*Email, \*Password, and \*Re-enter Password. A note below the password fields states: '(Passwords must be a minimum of 8 characters and include: 1 lowercase letter, 1 uppercase letter, and 1 number)' and '\*Denotes this entry is mandatory'. The 'User Agreements' section contains a checkbox for 'By clicking on this box, I verify that I have read and (I) acknowledge my agreement, as the Covered Entity, to the terms of the HIPAA/Business Associate Agreement, and (II) I agree to the Website Access Terms of Use and Privacy Policy.' and a 'Save' button. An orange arrow points from the 'Save' button to the 'Registration Confirmation' screen below.

To View **WEBSITE ACCESS TERMS OF USE, HIPAA/ BUSINESS ASSOCIATE TERMS OF USE, PRIVACY POLICY** click the hyperlink. When ready, click the check box to indicate agreement and then click **SAVE**.

The Registration Confirmation screen will display.

The screenshot shows the 'Registration Confirmation' screen. It has a dark blue header with the text 'Registration Confirmation' and a close button (X). The main content area is white and contains the text 'Thank You!' and 'Your registration was successful.' At the bottom right, there is an 'OK' button. An orange arrow points from the 'OK' button to the text 'Click OK.' on the left.

Click **OK**.



**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**

# STEP 1: CREATING AN ENROLLMENT REFERRAL

Enrollment referral requests can be created in 3 steps.

**STEP 1:** Enter the patient information, select or add the prescriber, select or add an office contact and the product information.

Prescriber Information:

- If you are requesting an enrollment referral for the first time, you need to assign a prescriber to your username/password
- If you are a returning user, prescriber information will populate automatically

Product Information:

- Please be sure to include the product dose (m) per administration, ICD-10 diagnosis code(s), and the expected site of administration.

Identify the patient.  
Enter his or her  
information.

Click on **Add New  
Prescriber** (see pg 7).

Click on **Add New  
Office Contact**  
(see pg 8).

After entering the  
required information,  
click **Next** to confirm.

The screenshot shows the 'Step 1: Patient Information' form. The form is divided into two main sections: 'Patient Information' and 'Select Product'. The 'Patient Information' section includes fields for First Name, Last Name, Address, Zip, City, State, Date of Birth, Gender (Male/Female), Home Phone, Cell Phone, Email Address, Prescriber, and Office Contact. The 'Select Product' section includes fields for Primary ICD-10-CM Diagnosis Code, Secondary ICD-10-CM Diagnosis Code, and a section for 'Specify previous therapies patient has received' with checkboxes for Platinum-containing chemotherapy, Programmed death receptor-1 (PD-1) inhibitor, and Programmed death-ligand 1 (PD-L1) inhibitor. There are also checkboxes for 'Expected Site of Administration' (Physician Office, Outpatient Hospital Setting, Other). The form has a 'Next' button at the bottom right. Arrows from the text on the left point to the 'Add New Prescriber' and 'Add New Office Contact' buttons, and the 'Next' button.



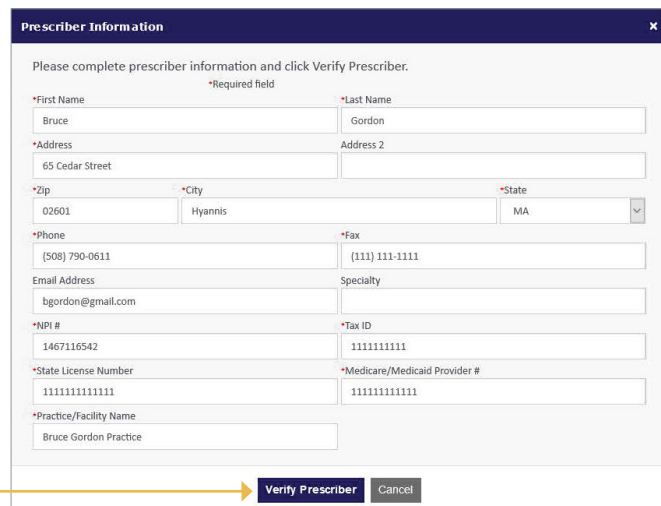
PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

# STEP 1:

## CREATING AN ENROLLMENT REFERRAL CONT.

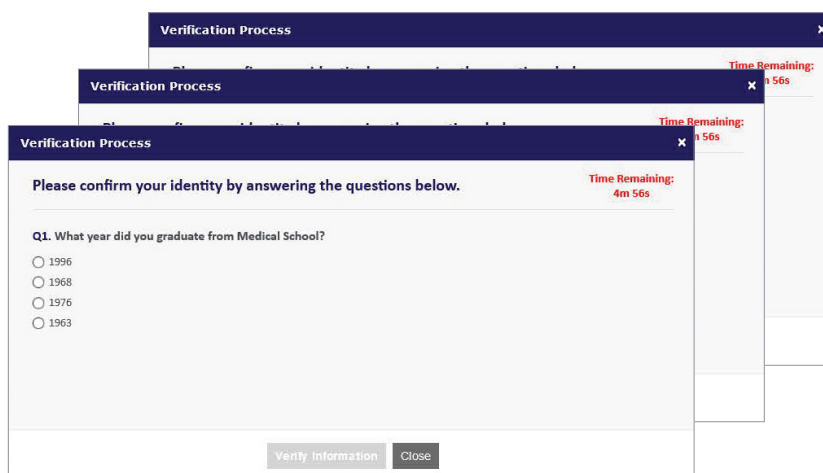
On the Prescriber Information page you will add the prescriber's:

- First and Last Name
- Address, City, State and Zip
- Email Address, Phone, and Fax
- NPI and TAX ID
- State License Number
- Medicare/Medicaid Provider #
- Practice/Facility Name



The 'Prescriber Information' form is a web-based interface for entering prescriber details. It includes fields for First Name, Last Name, Address, City, State, Zip, Phone, Fax, Email Address, Specialty, NPI #, Tax ID, State License Number, Medicare/Medicaid Provider #, and Practice/Facility Name. A 'Verify Prescriber' button is located at the bottom right of the form.

After clicking **Verify Prescriber** from the popup, the user will be presented with a series of questions.



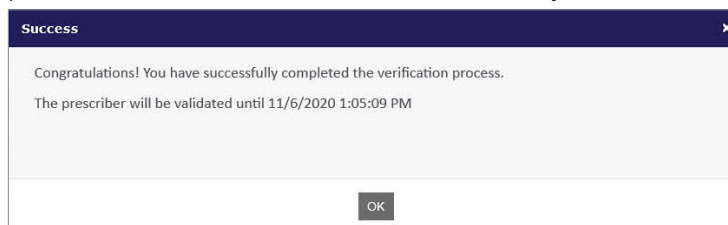
The 'Verification Process' form is a web-based interface for confirming identity. It displays a question: 'Q1. What year did you graduate from Medical School?' with radio button options for 1996, 1968, 1976, and 1963. A 'Time Remaining: 4m 56s' countdown timer is shown in the top right corner. The form includes 'Verify Information' and 'Close' buttons at the bottom.

Each question must be answered correctly (there will be a countdown displayed for the user) for the prescriber to be considered verified and ready to use on the site.

If the user is unable to answer all questions correctly, they will see an alert and can try again with a new series of questions

Once the total attempts (within a set) are exhausted, an alert will be displayed instructing to try again in an hour, or call for additional support.

Once the user answers all the questions successfully, they will receive an alert and the prescriber will be considered verified and ready to be used on the site.



The 'Success' alert is a web-based interface displaying a message: 'Congratulations! You have successfully completed the verification process. The prescriber will be validated until 11/6/2020 1:05:09 PM'. An 'OK' button is located at the bottom right of the alert.

**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**

**Help desk  
contact number:**  
1-888-402-0627

**Business hours:**  
Monday - Friday  
8:30am - 8:00pm ET





# STEP 1:

## CREATING AN ENROLLMENT REFERRAL CONT.

You will return to the Patient Information screen. Next, identify a person who will be available to answer questions about the enrollment referral request.

**Step 1**  
Enter patient-specific information and select a Product.

**Patient Information**

\*First Name

Jack

\*Last Name

Black

\*Address

11 Main Street

\*Zip

07078

\*City

Short Hills

\*State

NJ

\*Date of Birth

12/12/1960

\*Gender

☒ Male ☐ Female

\*Home Phone

(111) 111-1111

Cell Phone

Email Address

\*Prescriber

Bruce Gordon

Address 1: 65 Cedar Street

Address 2:

Zip: 02601

City: Hyannis

State: MA

Email: brucegordon@gmail.com

Phone: 508-790-0611

Fax: 508-790-0589

NPI #: 1467446542

Tax ID: 1111111111

\*Office Contact

Add New Prescriber

**Select Product**

\* PADCEV™ (enfortumab vedotin-efv)

Patient Dose per Administration:  mg

\*Primary ICD-10-CM Diagnosis Code

Secondary ICD-10-CM Diagnosis Code

Specify previous therapies patient has received:

Platinum-containing chemotherapy

Programmed death receptor-1 (PD-1) inhibitor

Programmed death-ligand 1 (PD-L1) inhibitor

\*Expected Site of Administration:

☐ Physician Office

☐ Outpatient Hospital Setting

☐ Other

Add New Office Contact

Next

Select your office contact, or for first time users, click, **Add New Office Contact**.



PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

# STEP 1: CREATING AN ENROLLMENT REFERRAL CONT.

Click **Save**.

**Office Contact Information** ✕

Please complete contact information and click Save. \*Required field

*First Name Peter	*Last Name Pasrker
*Email Address pparker@gmail.com	*Phone (111) 111-1111

**Save** **Cancel**

Click **Next**.

**Step 1**  
Enter patient-specific information and select a Product.

**Patient Information** \*Required field

*First Name Jack	*Last Name Black
*Address 11 Main Street	
*Zip 07078	*City Short Hills
*State NJ	
*Date of Birth 12/12/1960	*Gender <input checked="" type="radio"/> Male <input type="radio"/> Female
*Home Phone (111) 111-1111	Cell Phone
Email Address	
*Prescriber Bruce Gordon	
Address 1: 65 Cedar Street Address 2: Zip: 02601 City: Hyannis State: MA Email: brucegordon@gmail.com Phone: 508-790-0611 Fax: 508-790-0589 NPI #: 1467446542 Tax ID: 1111111111	
*Office Contact Jenny Smith	
Email Address: jsmith@gmail.com Phone: 111-111-1111	

**Add New Prescriber** **Add New Office Contact**

**Select Product**

\* PADCEV™ (enfortumab vedotin-ejfv)  
Patient Dose per Administration:  mg

\*Primary ICD-10-CM Diagnosis Code  Secondary ICD-10-CM Diagnosis Code

Specify previous therapies patient has received:  
Platinum-containing chemotherapy

Programmed death receptor-1 (PD-1) inhibitor

Programmed death-ligand 1 (PD-L1) inhibitor

\*Expected Site of Administration:  
☐ Physician Office  
☐ Outpatient Hospital Setting  
☐ Other

**Next**



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## STEP 2: CREATING AN ENROLLMENT REFERRAL

**STEP 2:** Enter Primary Medical Insurance information; Secondary Medical Insurance information and Prescription Plan (if applicable); and upload insurance cards and relevant documents.

For Primary Insurance enter the Plan Name, Subscriber's Name, Member ID, and Group ID.

Secondary Medical Insurance is optional (if applicable). Complete the Plan Name, Subscriber's Name, Member ID and Group ID.

Prescription Plan is optional. Complete the Prescription Plan, Policy Holder Name, Policy #, Rx BIN, PCN and Group ID.

Step 2

Enter patient insurance information and add other documentation.

Insurance Information

Primary Medical Insurance (Required)

\*Plan Type

Private/Commercial

\*Plan Name

Aetna

\*Subscriber's Name

John Doe

\*Policy #

111111111111111111111111

\*Group #

11111

Insurance Phone

Secondary Medical Insurance (Optional)

Plan Type

Prescription Plan

Plan Type

Upload Scanned Insurance Card(s)

Accepted file types: PDF, JPG, PNG, GIF

Upload

0 file(s) selected

Upload Relevant Documents

Accepted file types: PDF, JPG, PNG, GIF

Upload

0 file(s) selected

Previous

Next

## STEP 2: CREATING AN ENROLLMENT REFERRAL CONT.

To complete Step 2, upload the following documents: An image of the Insurance Card(s) both front and back, and other communications from the Insurance Company.

**Step 2**  
Enter patient insurance information and add other documentation.

**Insurance Information**  
Primary Medical Insurance (Required)  
\*Plan Type  
Private/Commercial  
\*Plan Name  
Aetna  
\*Subscriber's Name  
John Doe  
\*Policy #  
111111111111111111111111  
\*Group #  
11111  
Insurance Phone  
  
Secondary Medical Insurance (Optional)  
Plan Type  
  
Prescription Plan  
Plan Type  
  
**Upload Scanned Insurance Card(s)**  
Accepted file types: PDF, JPG, PNG, GIF  
Upload 0 file(s) selected  
  
**Upload Relevant Documents**  
Accepted file types: PDF, JPG, PNG, GIF  
Upload 0 file(s) selected  
  
Previous Next

To Attach Scanned Insurance Cards, click **Upload**.

To Attach Relevant Documents, click **Upload**.

Click **Next**.



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## STEP 3: CREATING AN ENROLLMENT REFERRAL

**STEP 3:** Review the enrollment referral request and make any changes, if applicable.

To make any changes,  
click **Edit**.

Once you complete  
your review, click  
**Add Signature**.

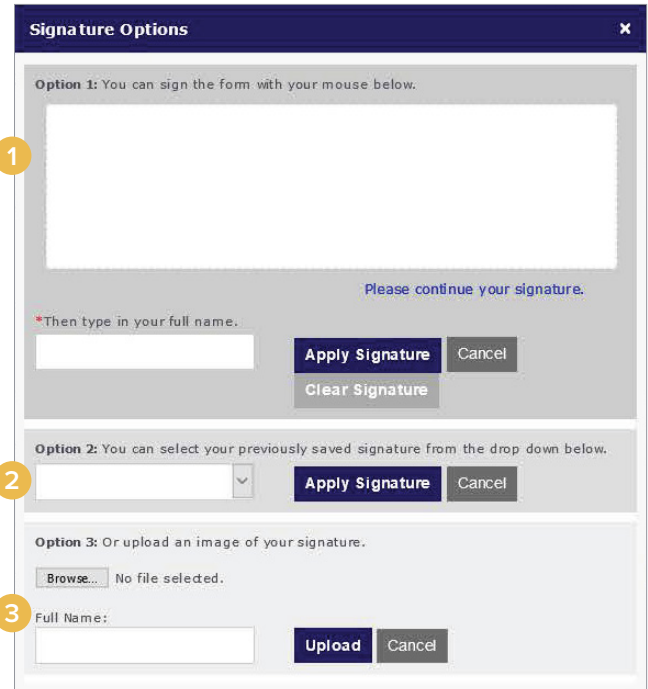
<b>Patient Information</b> <span>Edit</span>		<b>Product Selection</b> <span>Edit</span>
JOHN DOE 12 Main Street Florham Park, NJ 07932 PRIMARY PHONE: (111) 111-1111 EMAIL:		SEX: MALE DATE OF BIRTH: 11/12/1950 CELL PHONE: PADCEV® 20 mg vial Diagnosis: 10
<b>Insurance Information</b> <span>Edit</span>		
PRIMARY INSURANCE Aetna Subscriber: John Doe 111111111111111111111111 GROUP#: 111111 PHONE:	SECONDARY INSURANCE Subscriber: GROUP#: PHONE:	PRESCRIPTION INSURANCE Subscriber: RXGRP#: PCN: RXBIN#: PHONE:
<b>Insurance Card</b>	<b>Supporting Documentation</b>	
<b>Upload</b>	<b>Upload</b>	
<b>Prescriber Information</b> <span>Edit</span>		<b>Digital Signature</b>
Bruce Gordon NPI: 1467446542 Taxid: 1111111111  Staff Contact: Peter Parker Phone: (111) 111-1111 Email: pparker@gmail.com		65 Cedar Street Hyannis, MA 02601 bgordon@gmail.com Phone: (508) 790-0611 Fax: (508) 790-0589  <b>Add Signature</b>
<b>Provider Attestation</b>		
<p>By my signature above, I verify that I am the prescribing physician or authorized employee at the treating facility/practice and that the information being disclosed in this enrollment form is complete and accurate to the best of my knowledge. I understand that ASPN Pharmacies, LLC (ASPN) reserves the right at any time and for any reason, without my notice, to modify this enrollment form or to modify or discontinue any services or assistance provided through this Program. Finally, I authorize ASPN as my designated agent to use and disclose my patient's protected health information as may be necessary for treatment, payment, and healthcare operations, including to verify the accuracy of any information provided, to verify patient eligibility, to provide access and reimbursement support and services for my patient ("Services"). The prescribing physician has determined that the Astellas and Seattle Genetics Product for which we are requesting Services is medically appropriate for the patient and has been explained to the patient. Finally, I allow ASPN to email me regarding prescription status and insurance coverage updates.</p>		
<a href="#">Previous</a>		<b>Create Enrollment</b>



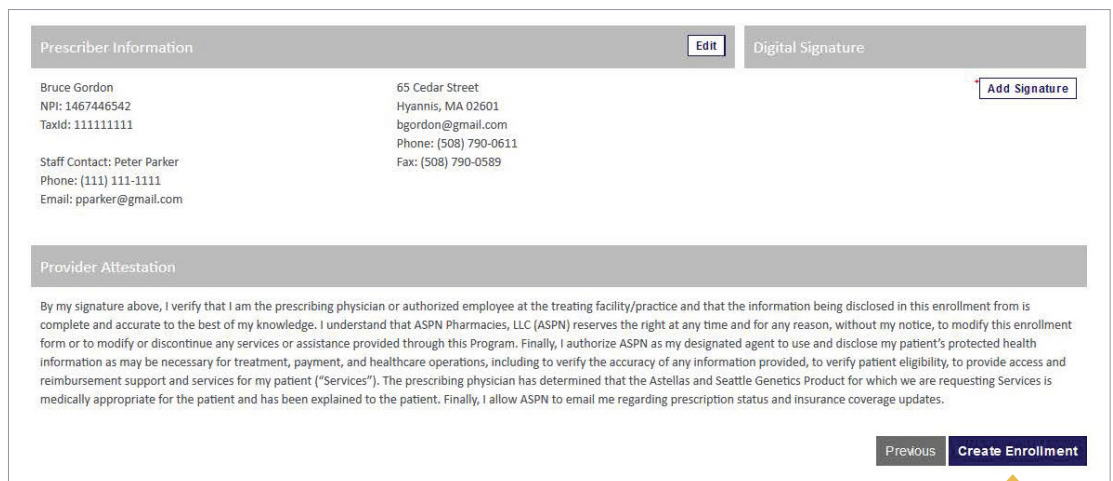
**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE  
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## STEP 3: CREATING AN ENROLLMENT REFERRAL

- 1 Sign with your mouse (optional). Enter the full name of the prescriber (required). Then, click **Apply Signature**.
- 2 Apply a signature that has been previously saved. Then, click **Apply Signature**.
- 3 Upload a written signature in PDF, JPEG, PNG or GIF format. Then, click **Upload**.



The 'Signature Options' dialog box contains three sections. Section 1, 'Option 1: You can sign the form with your mouse below.', features a large white signature area, a text input field for the full name, and buttons for 'Apply Signature', 'Cancel', and 'Clear Signature'. Section 2, 'Option 2: You can select your previously saved signature from the drop down below.', includes a dropdown menu and 'Apply Signature' and 'Cancel' buttons. Section 3, 'Option 3: Or upload an image of your signature.', has a 'Browse...' button, a 'Full Name:' text input, and 'Upload' and 'Cancel' buttons. Numbered callouts 1, 2, and 3 point to the signature area, the dropdown menu, and the 'Upload' button respectively.



This form is divided into two main sections. The 'Prescriber Information' section on the left contains fields for Name (Bruce Gordon), NPI (1467446542), Taxid (111111111), Staff Contact (Peter Parker), and their respective phone and email addresses. The 'Digital Signature' section on the right includes an 'Add Signature' button. Below these is the 'Provider Attestation' section with a detailed legal disclaimer. At the bottom right, there are 'Previous' and 'Create Enrollment' buttons. An orange arrow points from the 'Create Enrollment' button to the 'When you are ready to submit...' text on the left.

When you are ready to submit, click **Create Enrollment**.

A message will display confirming that you created the enrollment referral request successfully.

### Enrollment Complete

You can review the status of all your enrollment referrals by clicking [here](#), or you can create a new enrollment referral by clicking [here](#).

**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**



# VIEWING MY REQUEST

Home My Profile **My Referrals** Resources Contact Logout

To view your previous enrollment referrals, click **My Referrals**.

## CANCEL

**My Enrollment Referrals Status**

Prescriber First Name Or Last Name Filter

Prescriber Name	Patient Name	Product	Referral Submitted	Status	Info	Last Updated	Message
Bruce Gordon	John Doe 11/12/1950	PADCEV	11/6/2019 View Enrollment Form	Unassigned	1	11/06/2019 01:57 PM	View all messages

To view the uploaded attachments, click **Attachments**.

To upload additional documents, click **Upload**.

To close this display, click the **X** located on the top right corner.

**1 Patient Enrollment: John Doe**

**Status**

Enrollment Submitted: 11/6/2019

Cancelled:

**Attachments:**

INTAKEFORM\_34737.pdf

Insurance Card Additional Documentation

Upload Upload

**2 Status Info**

Change	Time Stamp	Status	Changed By
There is no history for this referral			

**3 Messages**

ENTER TEXT

Send Close

PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.



# MY PROFILE

To update your password, click **Change Password**.

**My Profile**  
You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account**  
\*Username  
bgordon  
**Change Password**  
\*Email address  
bgordon@gmail.com  
**My Account**  
\*Prescriber/Practice Name  
Bruce Gordon  
\*Phone Number  
(508) 790-0611  
Fax Number  
(508) 790-0589  
**Save** **Cancel**

**Prescriber Information**  
You can edit a specific prescriber's profile by clicking **Edit** below.  

First Name	Last Name	NPI	Verified	Edit
Bruce	Gordon	1467116542	NO	Verify
Bruce	Gordon	1467446542	YES	Edit

**Add New Prescriber**  
**Office Contact Profile**  
You can edit a specific contact profile by clicking **Edit** below.  

FirstName	LastName	Phone	Edit
Peter	Parker	1111111111	edit

**Add New Office Contact**

# CHANGING PRESCRIBER INFORMATION

You can update the Prescriber Information such as First Name, Last Name, Address, Phone and Fax.

To update Prescriber Information, click **Edit**.

**My Profile**  
You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account**  
\*Username  
bgordon  
**Change Password**  
\*Email address  
bgordon@gmail.com  
**My Account**  
\*Prescriber/Practice Name  
Bruce Gordon  
\*Phone Number  
(508) 790-0611  
Fax Number  
(508) 790-0589  
**Save** **Cancel**

**Prescriber Information**  
You can edit a specific prescriber's profile by clicking **Edit** below.  

First Name	Last Name	NPI	Verified	Edit
Bruce	Gordon	1467116542	NO	Verify
Bruce	Gordon	1467446542	YES	Edit

**Add New Prescriber**  
**Office Contact Profile**  
You can edit a specific contact profile by clicking **Edit** below.  

FirstName	LastName	Phone	Edit
Peter	Parker	1111111111	edit

**Add New Office Contact**

**Prescriber Information**  
Please complete prescriber information and click **Verify Prescriber**.  
\*Required field  
\*First Name  
Bruce  
\*Last Name  
Gordon  
\*Address  
65 Cedar Street  
Address 2  
\*Zip  
02601  
\*City  
Hyannis  
\*State  
MA  
\*Phone  
(508) 790-0611  
\*Fax  
(111) 111-1111  
Email Address  
bgordon@gmail.com  
Specialty  
\*NPI #  
1467116542  
\*Tax ID  
1111111111  
\*State License Number  
111111111111  
\*Medicare/Medicaid Provider #  
111111111111  
\*Practice/Facility Name  
Bruce Gordon Practice  
**Verify Prescriber** **Cancel**

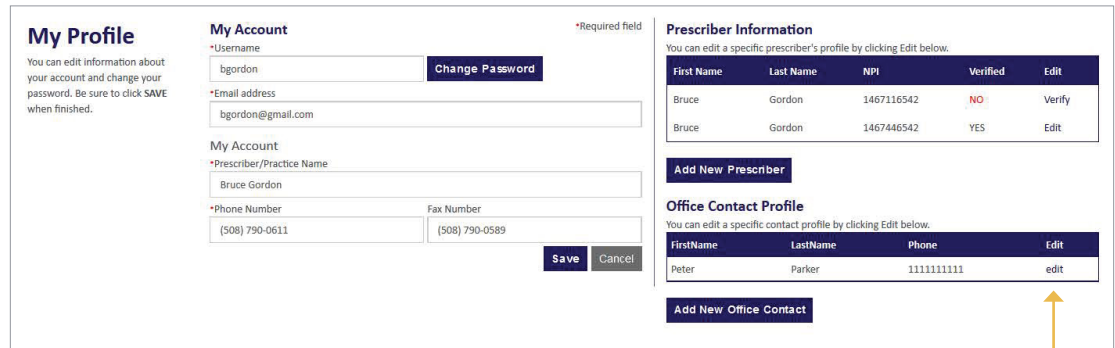
PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.





# CHANGING OFFICE CONTACT INFORMATION

You can update the Prescriber Information such as First Name, Last Name, Address, and Phone.



The screenshot shows a user profile page with three main sections: 'My Profile', 'My Account', and 'Prescriber Information'. The 'My Account' section contains fields for Username, Email address, Prescriber/Practice Name, Phone Number, and Fax Number. The 'Prescriber Information' section contains a table of prescriber data and an 'Add New Prescriber' button. The 'Office Contact Profile' section contains a table of office contact data and an 'Add New Office Contact' button. An orange arrow points from the 'Edit' link in the 'Office Contact Profile' table to a separate 'Office Contact Information' form.

**My Profile**  
You can edit information about your account and change your password. Be sure to click **SAVE** when finished.

**My Account** \*Required field

\*Username: bgordon **Change Password**

\*Email address: bgordon@gmail.com

**My Account**

\*Prescriber/Practice Name: Bruce Gordon

\*Phone Number: (508) 790-0611 Fax Number: (508) 790-0589 **Save** **Cancel**

**Prescriber Information**  
You can edit a specific prescriber's profile by clicking **Edit** below.

First Name	Last Name	NPI	Verified	Edit
Bruce	Gordon	1467116542	NO	Verify
Bruce	Gordon	1467446542	YES	Edit

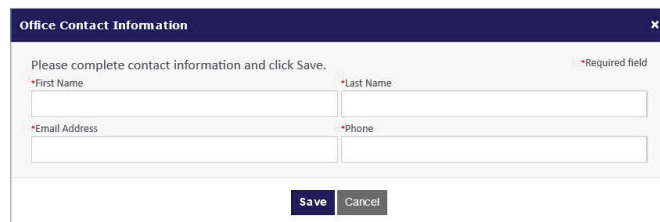
**Add New Prescriber**

**Office Contact Profile**  
You can edit a specific contact profile by clicking **Edit** below.

FirstName	LastName	Phone	Edit
Peter	Parker	1111111111	edit

**Add New Office Contact**

To update the Office Contact Information click **Edit**.



The 'Office Contact Information' form is a modal window with a title bar and a close button. It contains a message 'Please complete contact information and click Save.' and four required fields: First Name, Last Name, Email Address, and Phone. The form has 'Save' and 'Cancel' buttons at the bottom.

**Office Contact Information** ×

Please complete contact information and click Save. \*Required field

\*First Name: Last Name:

\*Email Address: Phone:

**Save** **Cancel**

To save your changes, click **Save**.



PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

## BOXED WARNING: SERIOUS SKIN REACTIONS

- PADCEV can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurred predominantly during the first cycle of treatment, but may occur later.
- Closely monitor patients for skin reactions.
- Immediately withhold PADCEV and consider referral for specialized care for suspected SJS or TEN or severe skin reactions.
- Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.

### Indication

PADCEV®, in combination with pembrolizumab, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC).

PADCEV, as a single agent, is indicated for the treatment of adult patients with locally advanced or mUC who:

- have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and platinum-containing chemotherapy, or
- are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.

## Important Safety Information

### Warnings and Precautions

**Skin reactions** Severe cutaneous adverse reactions, including fatal cases of SJS or TEN occurred in patients treated with PADCEV. SJS and TEN occurred predominantly during the first cycle of treatment but may occur later. Skin reactions occurred in 70% (all grades) of the 564 patients treated with PADCEV in combination with pembrolizumab in clinical trials. When PADCEV was given in combination with pembrolizumab, the incidence of skin reactions, including severe events, occurred at a higher rate compared to PADCEV as a single agent. The majority of the skin reactions that occurred with combination therapy included maculo-papular rash, macular rash and papular rash. Grade 3-4 skin reactions occurred in 17% of patients (Grade 3: 16%, Grade 4: 1%), including maculo-papular rash, bullous dermatitis, dermatitis, exfoliative dermatitis, pemphigoid, rash, erythematous rash, macular rash, and papular rash. A fatal reaction of bullous dermatitis occurred in one patient (0.2%). The median time to onset of severe skin reactions was 1.7 months (range: 0.1 to 17.2 months). Skin reactions led to discontinuation of PADCEV in 6% of patients.

Skin reactions occurred in 58% (all grades) of the 720 patients treated with PADCEV as a single agent in clinical trials. Twenty-three percent (23%) of patients had maculo-papular rash and 34% had pruritus. Grade 3-4 skin reactions occurred in 14% of patients, including maculo-papular rash, erythematous rash, rash or drug eruption, symmetrical drug-related intertriginous and flexural exanthema (SDRIFE), bullous dermatitis, exfoliative dermatitis, and palmar-plantar erythrodysesthesia. The median time to onset of severe skin reactions was 0.6 months (range: 0.1 to 8 months). Among patients experiencing a skin reaction leading to dose interruption who then restarted PADCEV (n=75), 24% of patients restarting at the same dose and 24% of patients restarting at a reduced dose experienced recurrent severe skin reactions. Skin reactions led to discontinuation of PADCEV in 3.1% of patients.

Monitor patients closely throughout treatment for skin reactions. Consider topical corticosteroids and antihistamines, as clinically indicated. For persistent or recurrent Grade 2 skin reactions, consider withholding PADCEV until Grade ≤1. Withhold PADCEV and refer for specialized care for suspected SJS, TEN or for Grade 3 skin reactions. Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.

**Hyperglycemia and diabetic ketoacidosis (DKA)**, including fatal events, occurred in patients with and without pre-existing diabetes mellitus, treated with PADCEV. Patients with baseline hemoglobin A1C ≥8% were excluded from clinical trials. In clinical trials of PADCEV as a single agent, 17% of the 720 patients treated with PADCEV developed hyperglycemia of any grade; 7% of patients developed Grade 3-4 hyperglycemia (Grade 3: 6.5%, Grade 4: 0.6%). Fatal events of hyperglycemia and DKA occurred in one patient each (0.1%). The incidence of Grade 3-4 hyperglycemia increased consistently in patients with higher body mass index and in patients with higher baseline A1C. The median time to onset of hyperglycemia was 0.5 months (range: 0 to 20 months). Hyperglycemia led to discontinuation of PADCEV in 0.7% of patients. Five percent (5%) of patients required initiation of insulin therapy for treatment of hyperglycemia. Of the patients who initiated insulin therapy for treatment of hyperglycemia, 66% (23/35)



discontinued insulin at the time of last evaluation. Closely monitor blood glucose levels in patients with, or at risk for, diabetes mellitus or hyperglycemia. If blood glucose is elevated (>250 mg/dL), withhold PADCEV.

**Pneumonitis /Interstitial Lung Disease (ILD)** Severe, life-threatening or fatal pneumonitis/ILD occurred in patients treated with PADCEV. When PADCEV was given in combination with pembrolizumab, 10% of the 564 patients treated with combination therapy had pneumonitis/ILD of any grade and 4% had Grade 3-4. A fatal event of pneumonitis/ILD occurred in two patients (0.4%). The incidence of pneumonitis/ILD, including severe events, occurred at a higher rate when PADCEV was given in combination with pembrolizumab compared to PADCEV as a single agent. The median time to onset of any grade pneumonitis/ILD was 4 months (range: 0.3 to 26 months).

In clinical trials of PADCEV as a single agent, 3% of the 720 patients treated with PADCEV had pneumonitis/ILD of any grade and 0.8% had Grade 3-4. The median time to onset of any grade pneumonitis/ILD was 2.9 months (range: 0.6 to 6 months).

Monitor patients for signs and symptoms indicative of pneumonitis/ILD such as hypoxia, cough, dyspnea or interstitial infiltrates on radiologic exams. Evaluate and exclude infectious, neoplastic and other causes for such signs and symptoms through appropriate investigations. Withhold PADCEV for patients who develop Grade 2 pneumonitis/ILD and consider dose reduction. Permanently discontinue PADCEV in all patients with Grade 3 or 4 pneumonitis/ILD.

**Peripheral neuropathy (PN)** When PADCEV was given in combination with pembrolizumab, 67% of the 564 patients treated with combination therapy had PN of any grade, 36% had Grade 2 neuropathy, and 7% had Grade 3 neuropathy. The incidence of PN occurred at a higher rate when PADCEV was given in combination with pembrolizumab compared to PADCEV as a single agent. The median time to onset of Grade  $\geq 2$  PN was 6 months (range: 0.3 to 25 months).

PN occurred in 53% of the 720 patients treated with PADCEV as a single agent in clinical trials including 38% with sensory neuropathy, 8% with muscular weakness and 7% with motor neuropathy. Thirty percent of patients experienced Grade 2 reactions and 5% experienced Grade 3-4 reactions. PN occurred in patients treated with PADCEV with or without preexisting PN. The median time to onset of Grade  $\geq 2$  PN was 4.9 months (range: 0.1 to 20 months). Neuropathy led to treatment discontinuation in 6% of patients.

Monitor patients for symptoms of new or worsening PN and consider dose interruption or dose reduction of PADCEV when PN occurs. Permanently discontinue PADCEV in patients who develop Grade  $\geq 3$  PN.

**Ocular disorders** were reported in 40% of the 384 patients treated with PADCEV as a single agent in clinical trials in which ophthalmologic exams were scheduled. The majority of these events involved the cornea and included events associated with dry eye such as keratitis, blurred vision, increased lacrimation, conjunctivitis, limbal stem cell deficiency, and keratopathy. Dry eye symptoms occurred in 30% of patients, and blurred vision occurred in 10% of patients, during treatment with PADCEV. The median time to onset to symptomatic ocular disorder was 1.7 months (range: 0 to 30.6 months). Monitor patients for ocular disorders. Consider artificial tears for prophylaxis of dry eyes and ophthalmologic evaluation if ocular symptoms occur or do not resolve. Consider treatment with ophthalmic topical steroids, if indicated after an ophthalmic exam. Consider dose interruption or dose reduction of PADCEV for symptomatic ocular disorders.

**Infusion site extravasation** Skin and soft tissue reactions secondary to extravasation have been observed after administration of PADCEV. Of the 720 patients treated with PADCEV as a single agent in clinical trials, 1% of patients experienced skin and soft tissue reactions, including 0.3% who experienced Grade 3-4 reactions. Reactions may be delayed. Erythema, swelling, increased temperature, and pain worsened until 2-7 days after extravasation and resolved within 1-4 weeks of peak. Two patients (0.3%) developed extravasation reactions with secondary cellulitis, bullae, or exfoliation. Ensure adequate venous access prior to starting PADCEV and monitor for possible extravasation during administration. If extravasation occurs, stop the infusion and monitor for adverse reactions.



**Embryo-fetal toxicity** PADCEV can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during PADCEV treatment and for 2 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PADCEV and for 4 months after the last dose.

### **Adverse Reactions**

**Most common adverse reactions, including laboratory abnormalities (≥20%) (PADCEV in combination with pembrolizumab)** Increased aspartate aminotransferase (AST), increased creatinine, rash, increased glucose, PN, increased lipase, decreased lymphocytes, increased alanine aminotransferase (ALT), decreased hemoglobin, fatigue, decreased sodium, decreased phosphate, decreased albumin, pruritus, diarrhea, alopecia, decreased weight, decreased appetite, increased urate, decreased neutrophils, decreased potassium, dry eye, nausea, constipation, increased potassium, dysgeusia, urinary tract infection and decreased platelets.

Most common adverse reactions, including laboratory abnormalities (≥20%) (PADCEV monotherapy) Increased glucose, increased AST, decreased lymphocytes, increased creatinine, rash, fatigue, PN, decreased albumin, decreased hemoglobin, alopecia, decreased appetite, decreased neutrophils, decreased sodium, increased ALT, decreased phosphate, diarrhea, nausea, pruritus, increased urate, dry eye, dysgeusia, constipation, increased lipase, decreased weight, decreased platelets, abdominal pain, dry skin.

### **EV-302 Study: 440 patients with previously untreated la/mUC (PADCEV in combination with pembrolizumab)**

Serious adverse reactions occurred in 50% of patients treated with PADCEV in combination with pembrolizumab. The most common serious adverse reactions (≥2%) were rash (6%), acute kidney injury (5%), pneumonitis/ILD (4.5%), urinary tract infection (3.6%), diarrhea (3.2%), pneumonia (2.3%), pyrexia (2%), and hyperglycemia (2%). Fatal adverse reactions occurred in 3.9% of patients treated with PADCEV in combination with pembrolizumab including acute respiratory failure (0.7%), pneumonia (0.5%), and pneumonitis/ILD (0.2%).

Adverse reactions leading to discontinuation of PADCEV occurred in 35% of patients. The most common adverse reactions (≥2%) leading to discontinuation of PADCEV were PN (15%), rash (4.1%) and pneumonitis/ILD (2.3%). Adverse reactions leading to dose interruption of PADCEV occurred in 73% of patients. The most common adverse reactions (≥2%) leading to dose interruption of PADCEV were PN (22%), rash (16%), COVID-19 (10%), diarrhea (5%), pneumonitis/ILD (4.8%), fatigue (3.9%), hyperglycemia (3.6%), increased ALT (3%) and pruritus (2.5%). Adverse reactions leading to dose reduction of PADCEV occurred in 42% of patients. The most common adverse reactions (≥2%) leading to dose reduction of PADCEV were rash (16%), PN (13%) and fatigue (2.7%).

### **EV-103 Study: 121 patients with previously untreated la/mUC who were not eligible for cisplatin-containing chemotherapy (PADCEV in combination with pembrolizumab)**

**Serious adverse reactions** occurred in 50% of patients treated with PADCEV in combination with pembrolizumab; the most common (≥2%) were acute kidney injury (7%), urinary tract infection (7%), urosepsis (5%), sepsis (3.3%), pneumonia (3.3%), hematuria (3.3%), pneumonitis/ILD (3.3%), urinary retention (2.5%), diarrhea (2.5%), myasthenia gravis (2.5%), myositis (2.5%), anemia (2.5%), and hypotension (2.5%). Fatal adverse reactions occurred in 5% of patients treated with PADCEV in combination with pembrolizumab, including sepsis (1.6%), bullous dermatitis (0.8%), myasthenia gravis (0.8%), and pneumonitis/ILD (0.8%). Adverse reactions leading to discontinuation of PADCEV occurred in 36% of patients; the most common (≥2%) were PN (20%) and rash (6%). Adverse reactions leading to dose interruption of PADCEV occurred in 69% of patients; the most common (≥2%) were PN (18%), rash (12%), increased lipase (6%), pneumonitis/ILD (6%), diarrhea (4.1%), acute kidney injury (3.3%), increased ALT (3.3%), fatigue (3.3%), neutropenia (3.3%), urinary tract infection (3.3%), increased amylase (2.5%), anemia (2.5%), COVID-19 (2.5%), hyperglycemia (2.5%), and hypotension (2.5%). Adverse reactions leading to dose reduction of PADCEV occurred in 45% of patients; the most common (≥2%) were PN (17%), rash (12%), fatigue (5%), neutropenia (5%), and diarrhea (4.1%).



### **EV-301 Study: 296 patients previously treated with a PD-1/L1 inhibitor and platinum-based chemotherapy (PADCEV monotherapy)**

**Serious adverse reactions** occurred in 47% of patients treated with PADCEV; the most common ( $\geq 2\%$ ) were urinary tract infection, acute kidney injury (7% each), and pneumonia (5%). **Fatal adverse reactions** occurred in 3% of patients, including multiorgan dysfunction (1%), hepatic dysfunction, septic shock, hyperglycemia, pneumonitis/ILD, and pelvic abscess (0.3% each). **Adverse reactions leading to discontinuation** occurred in 17% of patients; the most common ( $\geq 2\%$ ) were PN (5%) and rash (4%). **Adverse reactions leading to dose interruption** occurred in 61% of patients; the most common ( $\geq 4\%$ ) were PN (23%), rash (11%), and fatigue (9%). **Adverse reactions leading to dose reduction** occurred in 34% of patients; the most common ( $\geq 2\%$ ) were PN (10%), rash (8%), decreased appetite, and fatigue (3% each).

### **EV-201, Cohort 2 Study: 89 patients previously treated with a PD-1/L1 inhibitor and not eligible for cisplatin-based chemotherapy (PADCEV monotherapy)**

Serious adverse reactions occurred in 39% of patients treated with PADCEV; the most common ( $\geq 3\%$ ) were pneumonia, sepsis, and diarrhea (5% each). **Fatal adverse reactions** occurred in 8% of patients, including acute kidney injury (2.2%), metabolic acidosis, sepsis, multiorgan dysfunction, pneumonia, and pneumonitis/ILD (1.1% each). **Adverse reactions leading to discontinuation** occurred in 20% of patients; the most common ( $\geq 2\%$ ) was PN (7%). **Adverse reactions leading to dose interruption** occurred in 60% of patients; the most common ( $\geq 3\%$ ) were PN (19%), rash (9%), fatigue (8%), diarrhea (5%), increased AST, and hyperglycemia (3% each). **Adverse reactions leading to dose reduction** occurred in 49% of patients; the most common ( $\geq 3\%$ ) were PN (19%), rash (11%), and fatigue (7%).

### **DRUG INTERACTIONS**

#### **Effects of other drugs on PADCEV (Dual P-gp and Strong CYP3A4 Inhibitors)**

Concomitant use with dual P-gp and strong CYP3A4 inhibitors may increase unconjugated monomethyl auristatin E exposure, which may increase the incidence or severity of PADCEV toxicities. Closely monitor patients for signs of toxicity when PADCEV is given concomitantly with dual P-gp and strong CYP3A4 inhibitors.

### **SPECIFIC POPULATIONS**

**Lactation** Advise lactating women not to breastfeed during treatment with PADCEV and for 3 weeks after the last dose.

**Hepatic impairment** Avoid the use of PADCEV in patients with moderate or severe hepatic impairment.



**PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE [CLICK HERE](#) FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.**