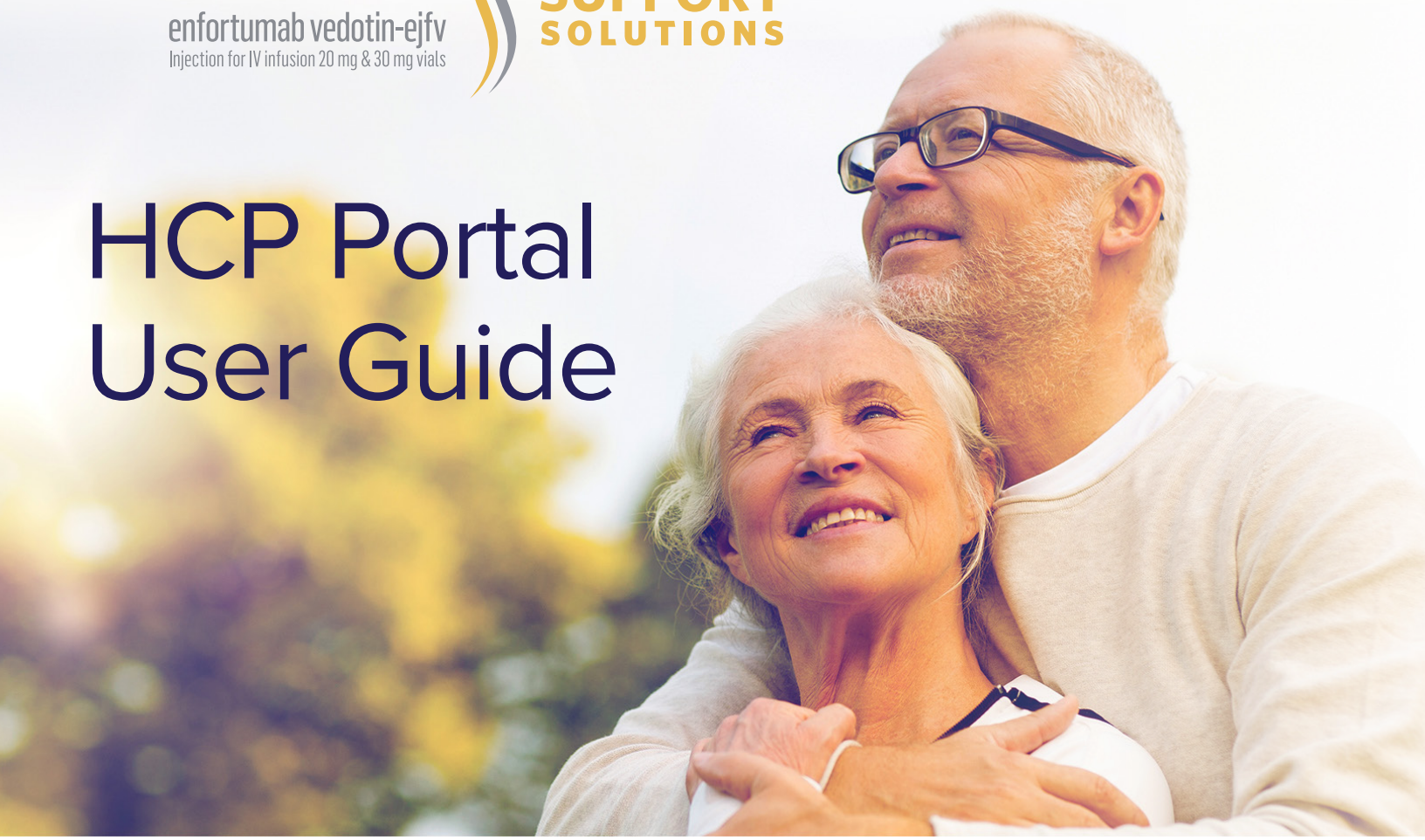
PADCEV®
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

SUPPORT℠ SOLUTIONS



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.

TABLE OF CONTENTS

astellas

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

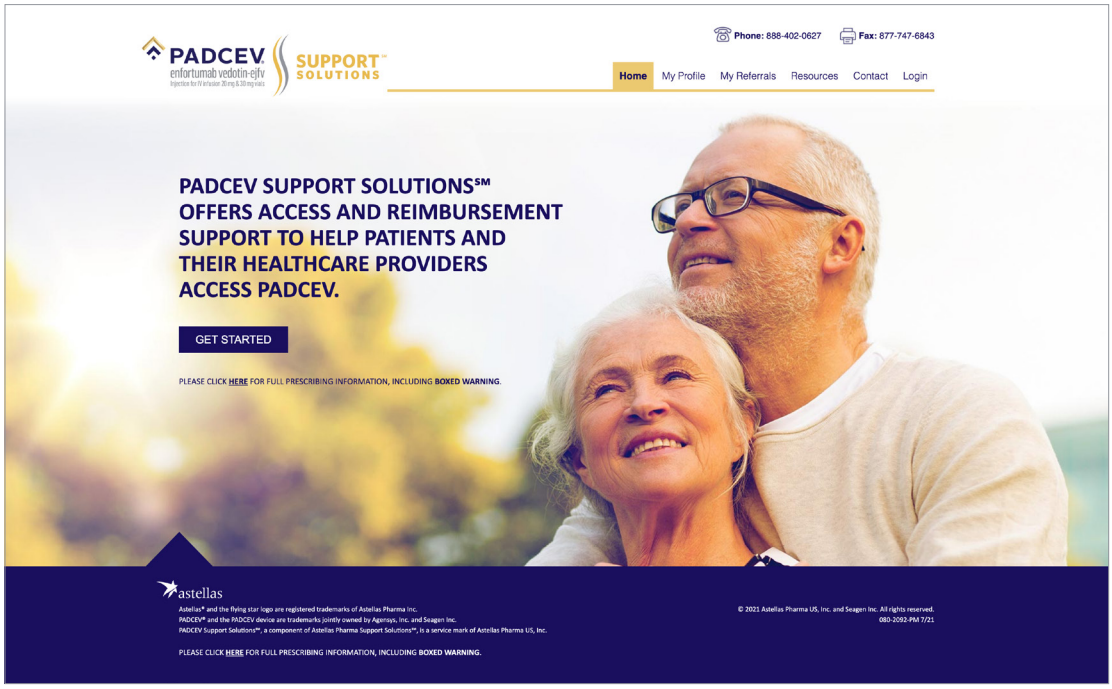
OVERVIEW

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

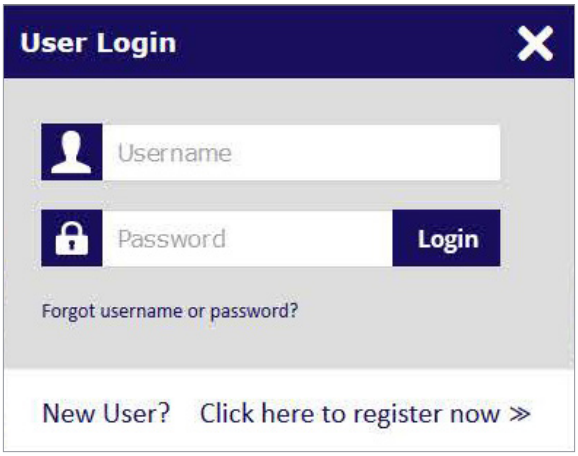
LOGGING ON

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.

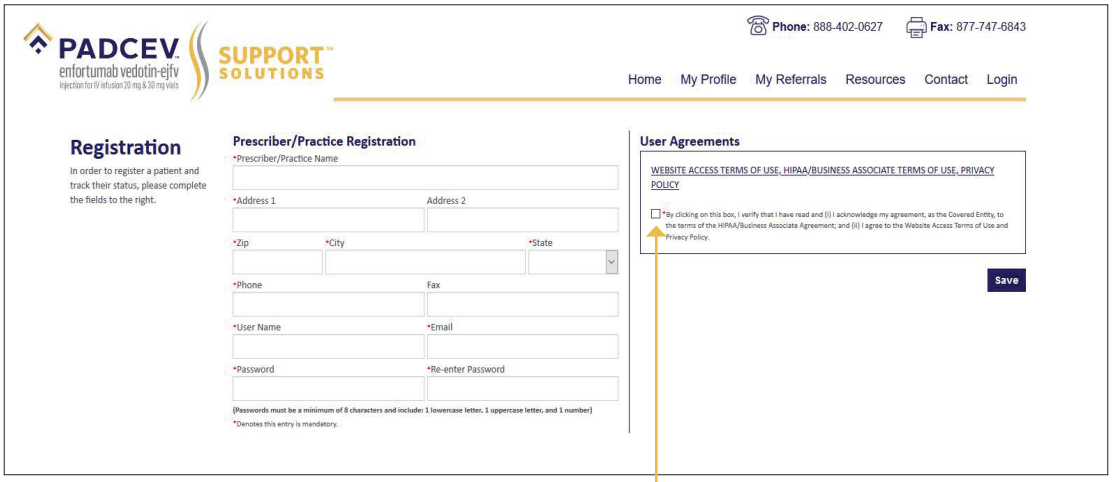
Returning Users: Click the **Login** button at the top right of the page. In the User Login modal that pops up, enter your User Name and Password, then click **Login**. Continue to page 6 of this document.



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

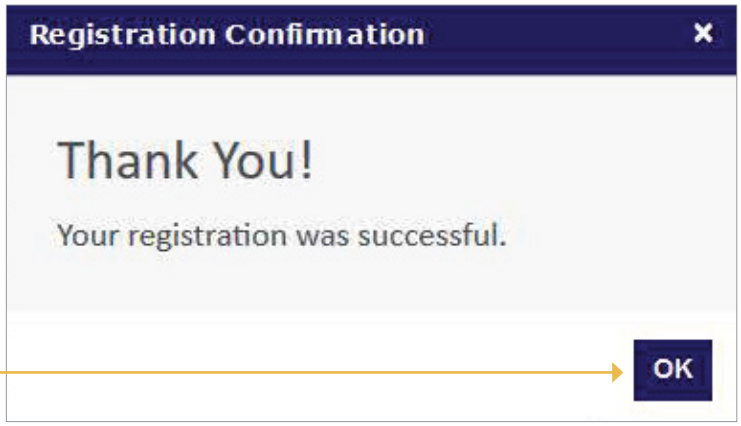
LOGGING ON CONT.

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



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.



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:

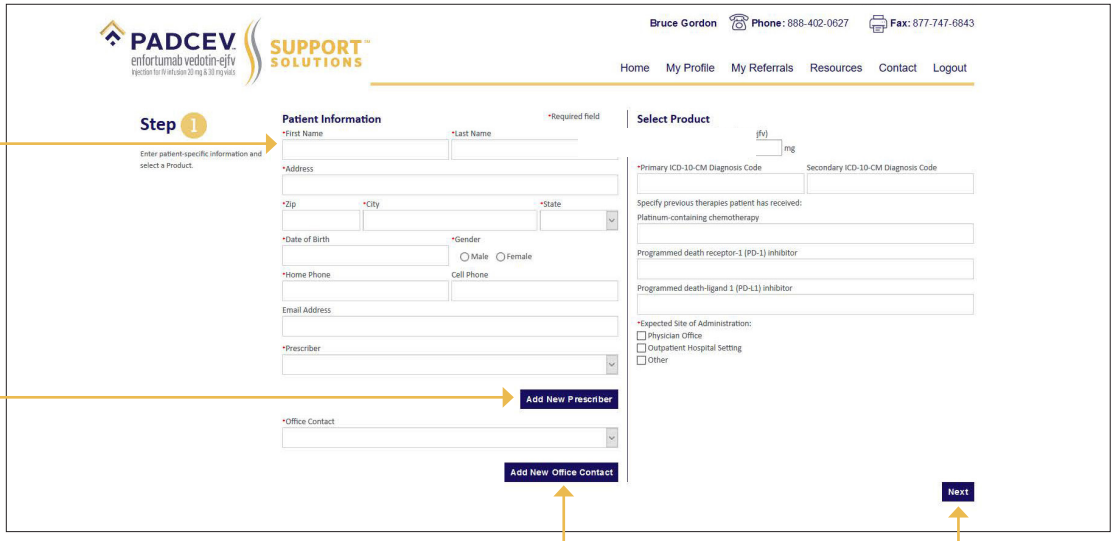
- Please be sure to include the product dose (m) per administration, ICD-10 diagnosis code(s), and the expected site of administration.

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.



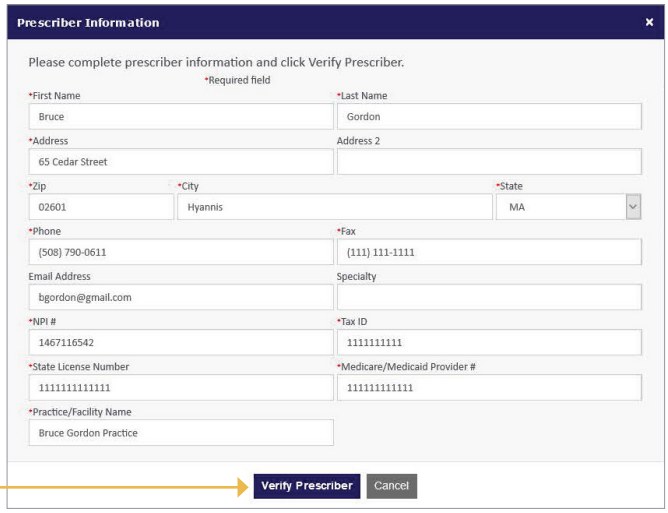
astellas

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

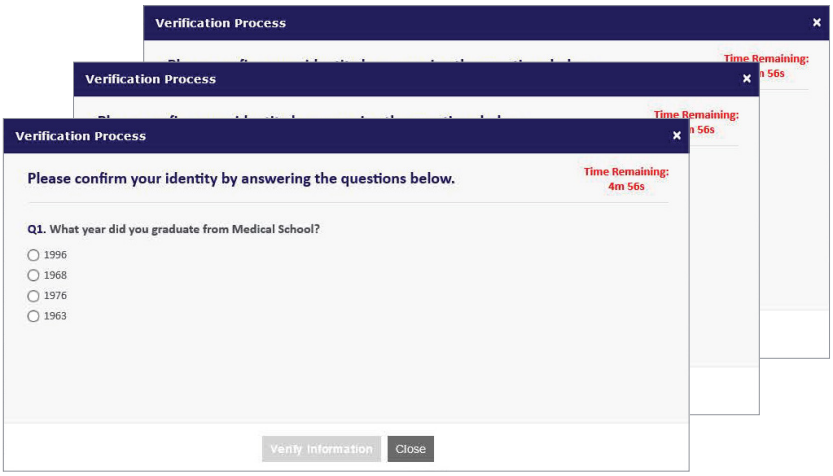
STEP 1:
CREATING AN ENROLLMENT REFERRAL CONT.

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



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

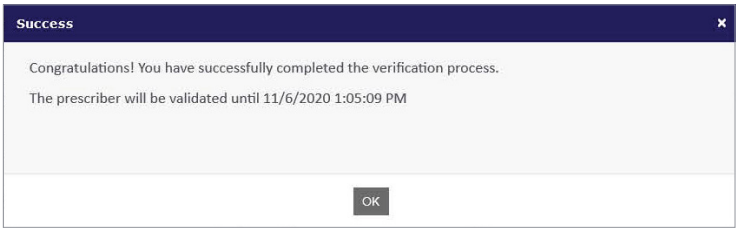


Each question must be answered correctly (there will be a countdown displayed for the user) for the prescriber to be considered verified and ready to use on the site.

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.



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

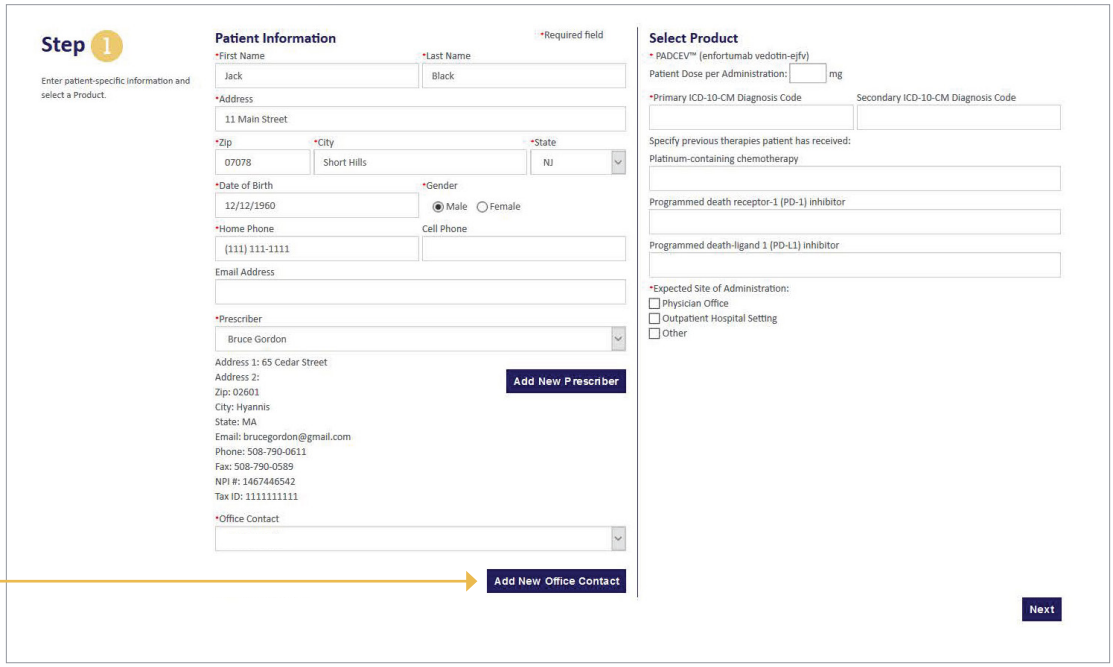
Help desk contact number:
1-888-402-0627

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

astellas

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.

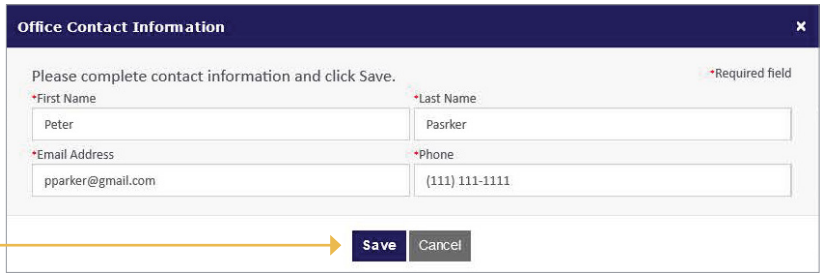


Select your office contact, or for first time users, click, **Add New Office Contact.**

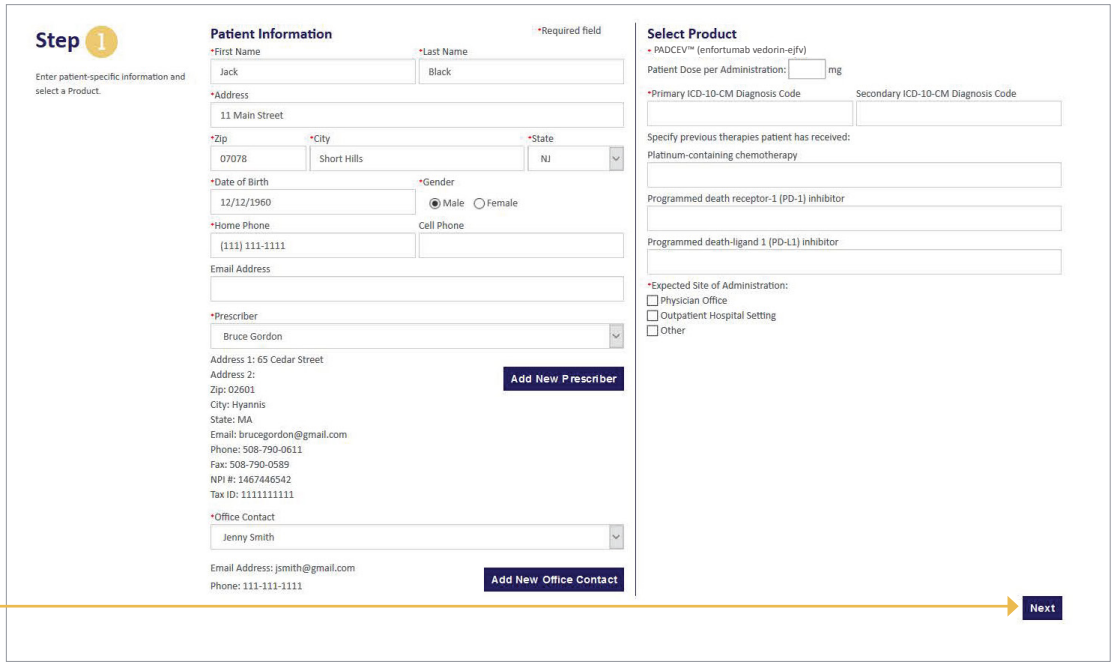
PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

STEP 1:
CREATING AN ENROLLMENT REFERRAL CONT.

Click **Save.**



Click **Next.**



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

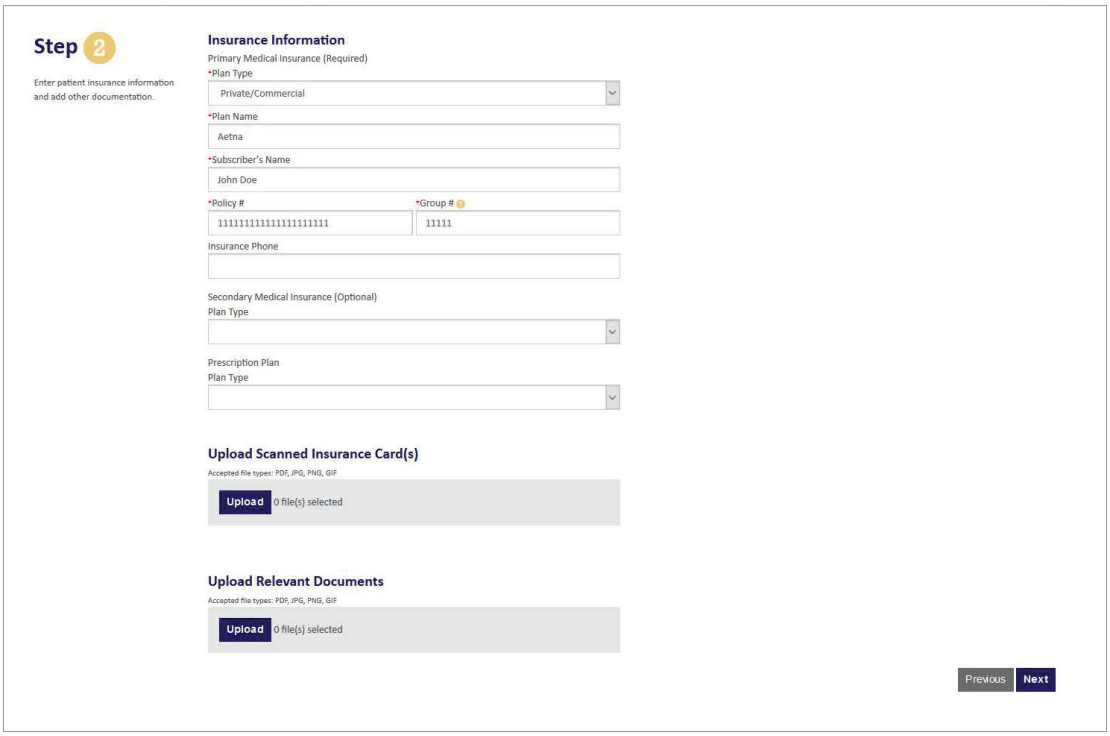
STEP 2:
CREATING AN ENROLLMENT REFERRAL

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.

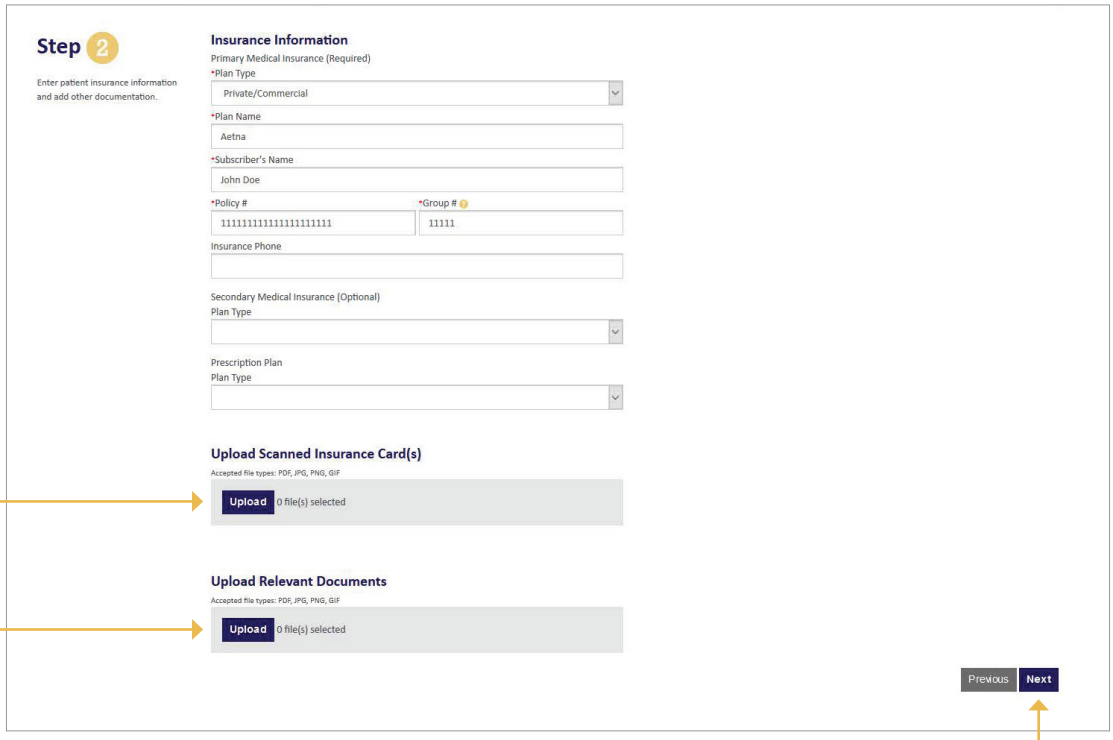
Prescription Plan is optional. Complete the Prescription Plan, Policy Holder Name, Policy #, Rx BIN, PCN and Group ID.



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

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.



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

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

Click **Next.**

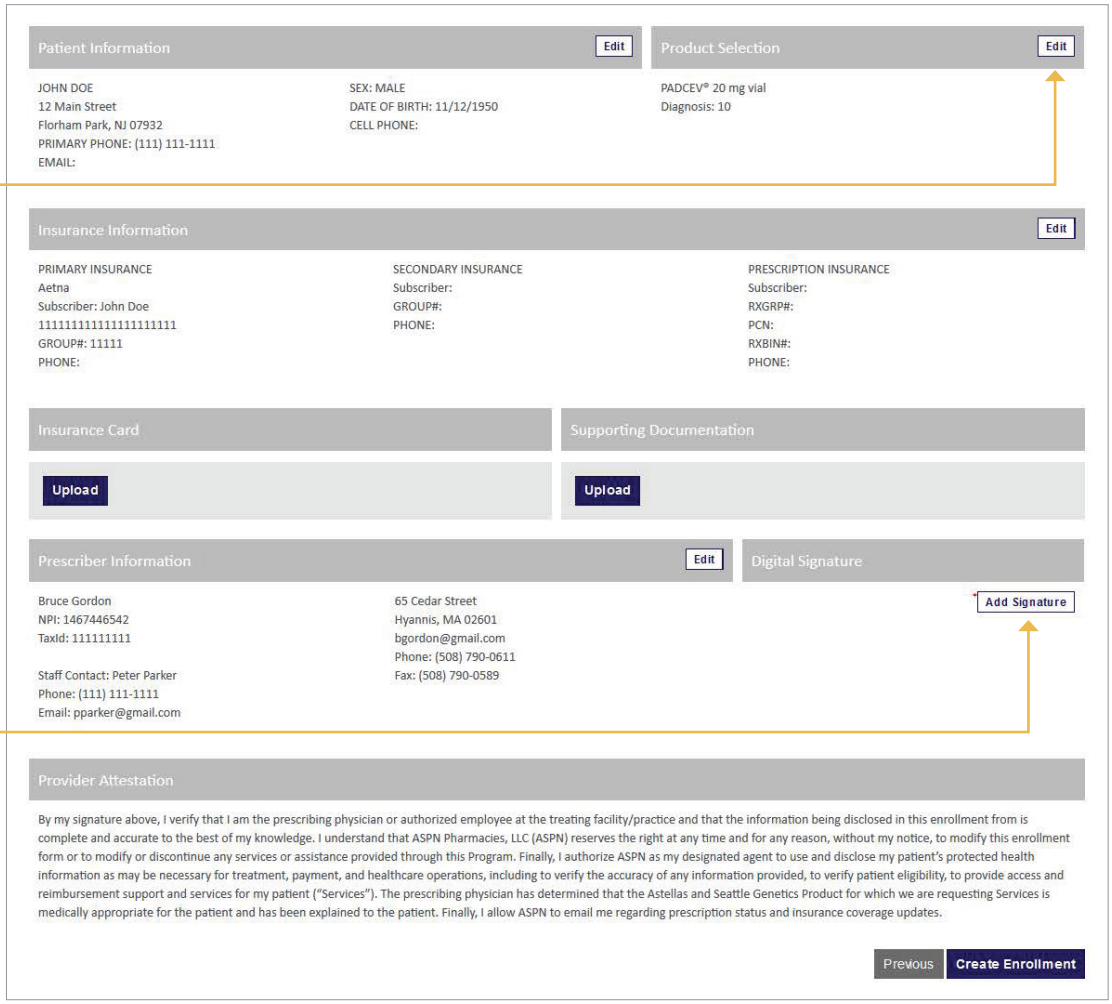
PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

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.**

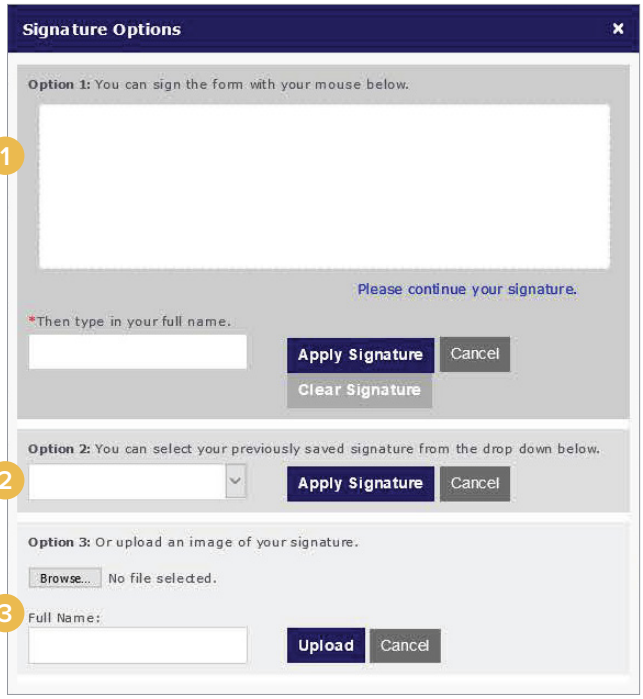
Once you complete your review, click **Add Signature.**

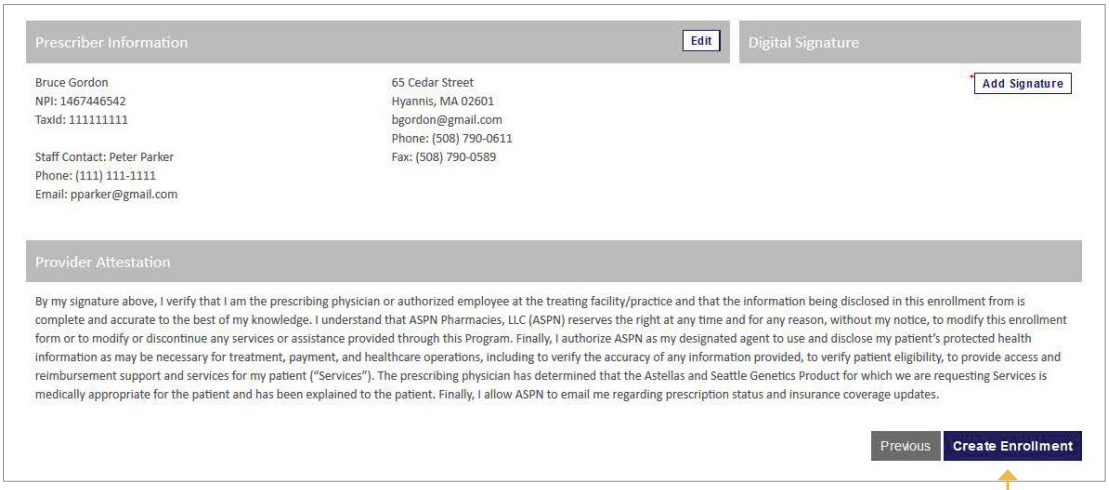


PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

STEP 3:
CREATING AN ENROLLMENT REFERRAL

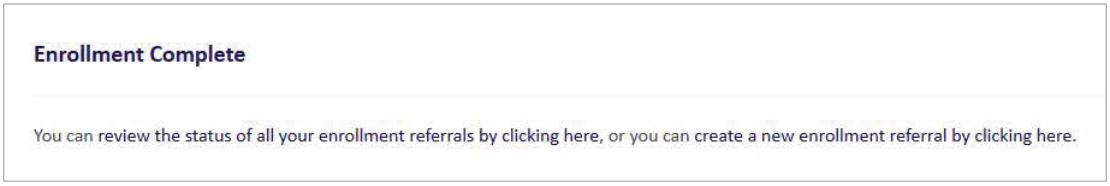
1. Sign with your mouse (optional). Enter the full name of the prescriber (required). Then, click **Apply Signature**.
2. Apply a signature that has been previously saved. Then, click **Apply Signature**.
3. Upload a written signature in PDF, JPEG, PNG or GIF format. Then, click **Upload**.





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

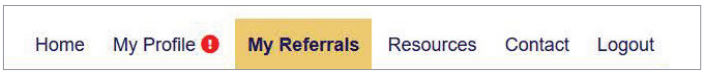
A message will display confirming that you created the enrollment referral request successfully.



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

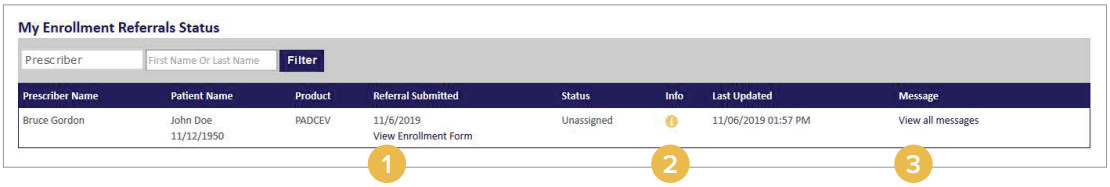
astellas

VIEWING MY REQUEST



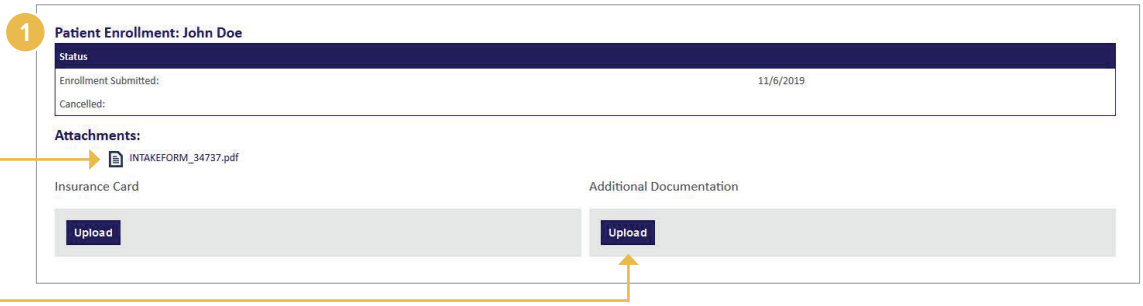
To view your previous enrollment referrals, click **My Referrals.**

CANCEL

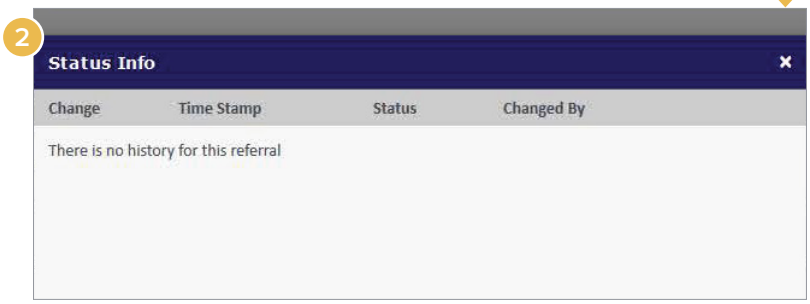


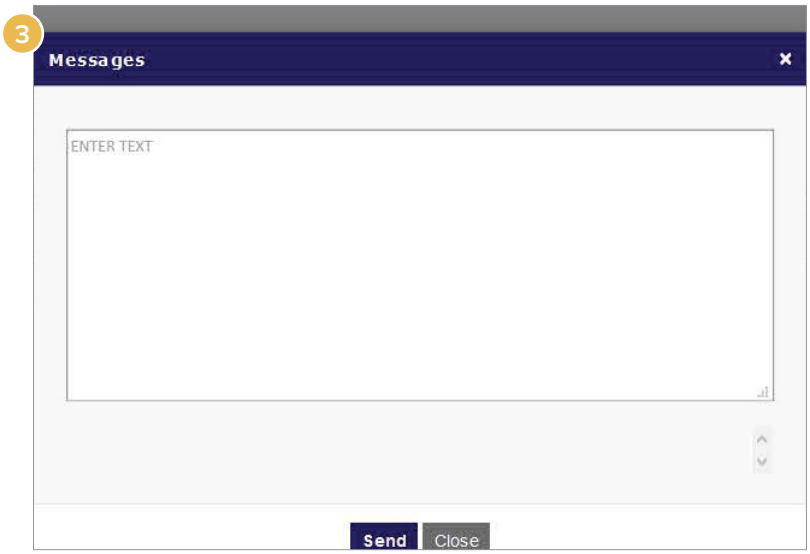
To view the uploaded attachments, click **Attachments.**

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



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



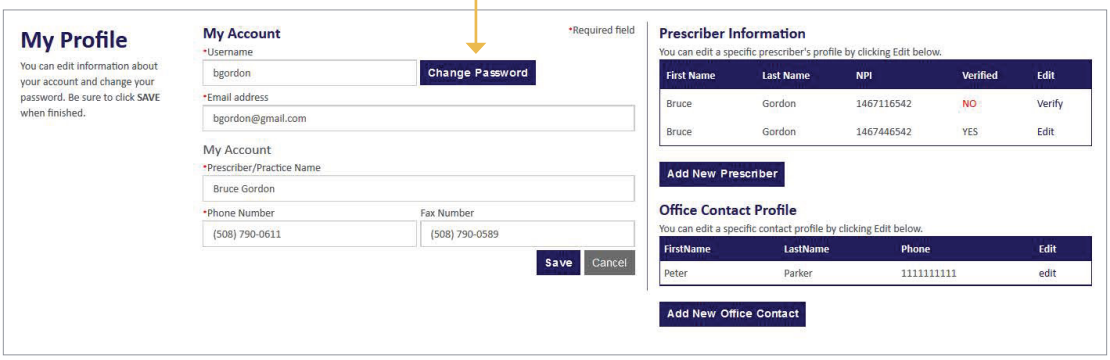


PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

astellas

MY PROFILE

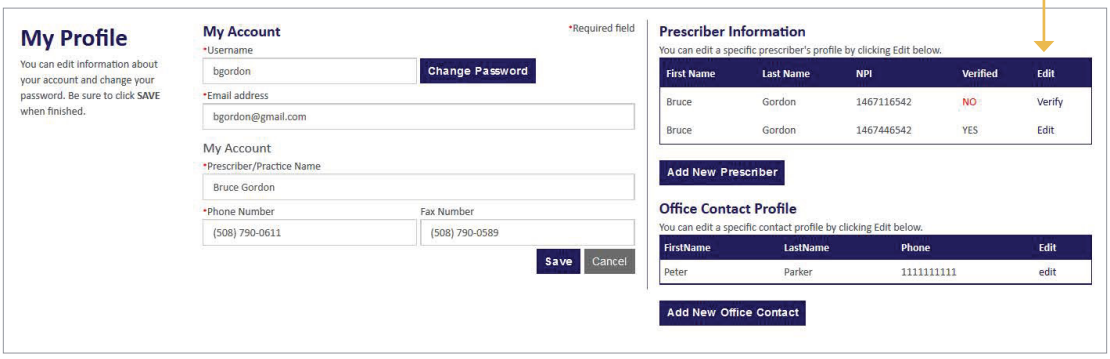
To update your password, click **Change Password.**

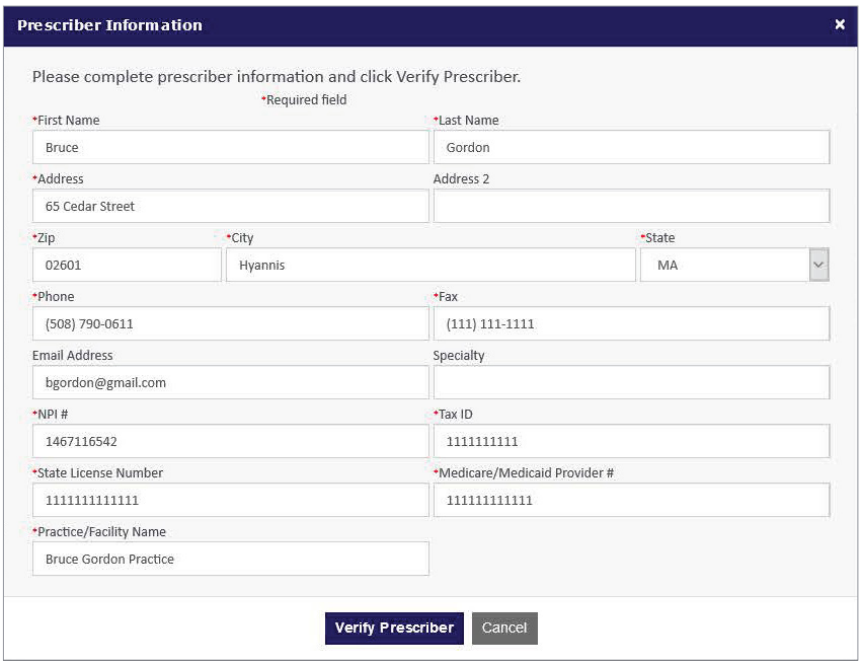


CHANGING PRESCRIBER INFORMATION

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

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



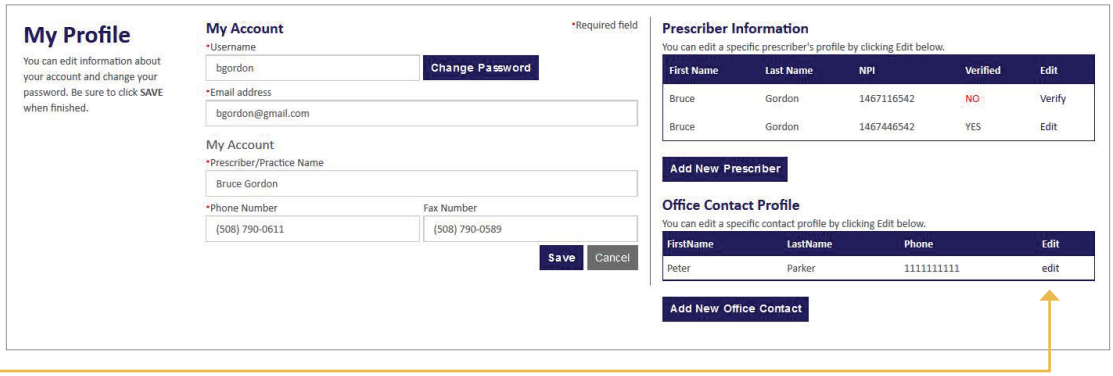


PLEASE SEE PAGES 15 TO 18 FOR THE IMPORTANT SAFETY INFORMATION. PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

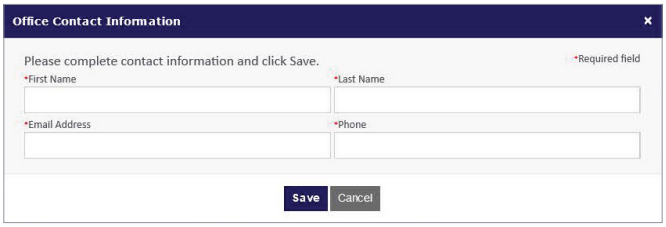
astellas

CHANGING OFFICE CONTACT INFORMATION

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



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



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)

PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

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 ≥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 ≥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 ≥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.

astellas

PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

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%).

astellas

PLEASE CLICK HERE FOR FULL PRESCRIBING INFORMATION, INCLUDING BOXED WARNING.

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 (≥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 (≥2%) were PN (5%) and rash (4%). **Adverse reactions leading to dose interruption** occurred in 61% of patients; the most common (≥4%) were PN (23%), rash (11%), and fatigue (9%). **Adverse reactions leading to dose reduction** occurred in 34% of patients; the most common (≥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 (≥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 (≥2%) was PN (7%). **Adverse reactions leading to dose interruption** occurred in 60% of patients; the most common (≥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 (≥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.