

PALFORZIA REMS Healthcare Setting Enrollment Form

PALFORZIA™ is available only through the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy); a restricted program. Only prescribers, healthcare settings, pharmacies, and patients enrolled in the program can prescribe, administer, dispense, and receive PALFORZIA.

INSTRUCTIONS

To become certified in the PALFORZIA REMS Program and administer PALFORZIA, a healthcare setting (HCS) must designate an Authorized Representative to:

1. Review the *Education Program for Healthcare Settings*.
2. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.
3. Complete and submit the *Healthcare Setting Enrollment Form* online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013.

Complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

HEALTHCARE SETTING INFORMATION

(*indicates required field)

Healthcare Setting Name*:		National Provider Identifier (NPI #)*:
Healthcare Setting Type*: <input type="checkbox"/> Independent Practice <input type="checkbox"/> Private Group Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital Ambulatory Clinic <input type="checkbox"/> Other		
Address 1*:		
Address 2*:		
City*:	State*:	ZIP*:
<input type="checkbox"/> If you are certifying more than one healthcare setting location for which the Authorized Representative is responsible, check this box and provide the information for each site below.		

AUTHORIZED REPRESENTATIVE INFORMATION

First Name*:		Last Name*:	
Role*:	<input type="checkbox"/> Physician <input type="checkbox"/> Physician Assistant <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Pharmacist	Reason for Form* (please select one):	
	<input type="checkbox"/> Nurse <input type="checkbox"/> Other Responsible Individual Designated by Healthcare Setting	<input type="checkbox"/> New Enrollment	
	<input type="checkbox"/> Practice Manager <input type="checkbox"/> Administrator	<input type="checkbox"/> New Authorized Representative	
Phone Number*:	Fax Number*:	Email Address*:	
Address 1*:			
Address 2*:			
City*:	State*:	ZIP*:	

HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT

I am the Authorized Representative designated by my Healthcare Setting to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following REMS requirements:

I will:

- o Oversee implementation of and ensure my healthcare setting's compliance with the PALFORZIA REMS requirements
- o Review the *Education Program for Healthcare Settings*
- o Have a certified prescriber on-site
- o Have healthcare provider(s) on-site to counsel each patient, and monitor for and manage anaphylaxis
- o Be able to manage anaphylaxis on-site
- o Train all relevant staff involved in dispensing and administering PALFORZIA, and **establish processes and procedures** to ensure that the following take place in my healthcare setting:

Before treatment initiation (first dose):

- o Verify the Initial Dose Escalation is for the enrolled patient

During treatment before dispensing the first dose of each Up-Dosing level:

- o Verify that the patient is enrolled in the REMS
- o Have a healthcare provider counsel the patient on the need to be monitored for anaphylaxis
- o Verify that the dose, as determined by the certified prescriber, is dispensed from the Office Dose Kit
- o Verify that the patient has injectable epinephrine

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HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT (Continued)

During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level:

- o Assess the patient for anaphylaxis for at least 60 minutes

At all times:

- o Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
- o Maintain records of dispensing and that all processes and procedures are in place and are being followed
- o Comply with audits carried out by Aimmune Therapeutics, Inc., or a third party acting on behalf of Aimmune Therapeutics, Inc., to ensure that all processes and procedures are in place and are being followed
- o Not distribute, transfer, loan, or sell PALFORZIA



Authorized Representative Signature *:

Date*:

Use this section to add all additional Healthcare Setting locations for which the same Authorized Representative will be responsible.

Healthcare Setting Name*:	National Provider Identifier (NPI #)*:
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Healthcare Setting Type*: <input type="checkbox"/> Independent Practice <input type="checkbox"/> Private Group Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital Ambulatory Clinic <input type="checkbox"/> Other
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Address 2:

City*:	State*:	ZIP*:
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Healthcare Setting Name*:	National Provider Identifier (NPI #)*:
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Healthcare Setting Type*: <input type="checkbox"/> Independent Practice <input type="checkbox"/> Private Group Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital Ambulatory Clinic <input type="checkbox"/> Other
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City*:	State*:	ZIP*:
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Healthcare Setting Name*:	National Provider Identifier (NPI #)*:
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Healthcare Setting Type*: <input type="checkbox"/> Independent Practice <input type="checkbox"/> Private Group Practice <input type="checkbox"/> Outpatient Clinic <input type="checkbox"/> Hospital Ambulatory Clinic <input type="checkbox"/> Other
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Address 1*:

Address 2:

City*:	State*:	ZIP*:
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Authorized Representative: Please PRINT your name and phone number here.

*Name _____	*Phone Number _____
Last	First

