

# Risk Evaluation and Mitigation Strategy (REMS) Document

## PALFORZIA [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp]

### REMS Program

## I. Administrative Information

Application Number: BLA 125696  
Application Holder: Aimmune Therapeutics, Inc.  
Initial REMS Approval: 01/2020

## II. REMS Goal

The goal of the PALFORZIA REMS Program is to mitigate the risk of anaphylaxis associated with PALFORZIA by:

1. Ensuring that healthcare providers who prescribe and healthcare settings that dispense and administer PALFORZIA are educated on the following:
  - a. the risk of anaphylaxis associated with the use of PALFORZIA
  - b. the Initial Dose Escalation and first dose of each Up-Dosing level must only be administered to patients in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.
2. Ensuring that the Initial Dose Escalation and the first dose of each Up-Dosing level of PALFORZIA are only dispensed and distributed to certified healthcare settings and only administered to patients in certified healthcare settings.
3. Ensuring that PALFORZIA is only dispensed and administered to patients who are informed, by enrolling in the PALFORZIA REMS Program, of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.

## III. REMS Requirements

**Aimmune Therapeutics, Inc. must ensure that healthcare providers, patients, healthcare settings, pharmacies, and wholesalers-distributors comply with the following requirements:**

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| <b>1. Healthcare providers who prescribe PALFORZIA must:</b> |  |
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| To become certified to prescribe                             | <ol style="list-style-type: none"><li>1. Review the PALFORZIA Prescribing Information.</li><li>2. Enroll in the REMS by completing the <a href="#">Prescriber Enrollment Form</a> and submitting it to the REMS Program.</li></ol>   |
| Before treatment initiation (first dose)                     | <ol style="list-style-type: none"><li>3. Enroll the patient by completing and submitting the <a href="#">Patient Enrollment Form</a> to the REMS Program. Provide a completed copy of the form to the patient.</li><li>4. Counsel the patient on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.</li><li>5. Assess the patient's supply of injectable epinephrine and provide prescription if necessary.</li></ol> |

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| During treatment;<br>before dispensing the<br>first dose of each<br>Up-Dosing level | 6. Assess the patient’s tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing. |
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| At all times | 7. Report treatment discontinuation or transfer of care to the REMS Program. |
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## **2. Patients who are prescribed PALFORZIA:**

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| Before treatment<br>initiation | <ol style="list-style-type: none"><li>1. Enroll in the REMS Program by completing the <a href="#">Patient Enrollment Form</a> with the prescriber. Enrollment information will be provided to the REMS Program.</li><li>2. Receive counseling from the prescriber on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and the first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.</li></ol> |
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| During treatment,<br>before the first dose of<br>each Up-Dosing level | <ol style="list-style-type: none"><li>3. Receive counseling from a healthcare provider on the need for monitoring for anaphylaxis.</li></ol> |
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| During treatment,<br>during and after<br>administration of the<br>Initial Dose Escalation<br>and the first dose of<br>each Up-Dosing level,<br>for at least 60 minutes | <ol style="list-style-type: none"><li>4. Be monitored for anaphylaxis at the healthcare setting.</li></ol> |
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| At all times | <ol style="list-style-type: none"><li>5. Report anaphylaxis to your healthcare provider.</li><li>6. Inform your healthcare provider if you need more injectable epinephrine.</li><li>7. Have injectable epinephrine available for immediate use.</li><li>8. Adhere to the safe use conditions: avoid peanuts and foods that contain peanuts.</li></ol> |
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## **3. Healthcare settings that dispense PALFORZIA must:**

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| To become certified to<br>dispense | <ol style="list-style-type: none"><li>1. Have healthcare provider(s) on-site to monitor for and manage anaphylaxis.</li><li>2. Have a certified prescriber on-site.</li><li>3. Be able to manage anaphylaxis on-site.</li><li>4. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.</li><li>5. Have the authorized representative review the <a href="#">Education Program for Healthcare Settings</a>.</li><li>6. Have the authorized representative enroll in the REMS Program by completing the <a href="#">Healthcare Setting Enrollment Form</a> and submitting it to the REMS Program.</li><li>7. Train all relevant staff involved in dispensing and administering PALFORZIA using the <a href="#">Education Program for Healthcare Settings</a>.</li><li>8. Establish processes and procedures to verify the Initial Dose Escalation is prescribed to initiate treatment and the dose, as determined by the certified prescriber, from the Office Dose Kit is dispensed to enrolled patients for the first dose of each Up-Dosing level.</li></ol> |
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|  | <ol style="list-style-type: none"> <li>9. Establish processes and procedures to verify the patient is monitored by a healthcare provider during and after the Initial Dose Escalation and the first dose of each Up-Dosing level.</li> <li>10. Establish processes and procedures to verify the patient has injectable epinephrine before the first dose of each Up-Dosing level.</li> </ol>  |
| Before administering (first dose)  | 11. Verify the Initial Dose Escalation is for the enrolled patient.   |
| During treatment; before the first dose of each Up-Dosing level  | <ol style="list-style-type: none"> <li>12. Verify that the patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS Program.</li> <li>13. Counsel the patient on the need for monitoring for anaphylaxis.</li> <li>14. Verify that the dose, as determined by the certified prescriber, is dispensed from the Office Dose Kit through the processes and procedures established as a requirement of the REMS Program.</li> <li>15. Verify that the patient has injectable epinephrine through the processes and procedures established as a requirement of the REMS Program.</li> </ol> |
| During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes | 16. Assess the patient for anaphylaxis through the processes and procedures established as a requirement of the REMS Program.   |
| To maintain certification to dispense  | 17. Have a new Authorized Representative enroll in the REMS Program by completing the <a href="#">Healthcare Setting Enrollment Form</a> if the authorized representative changes.  |
| At all times   | <ol style="list-style-type: none"> <li>18. Not distribute, transfer, loan or sell PALFORZIA.</li> <li>19. Maintain records of dispensing and that all processes and procedures are in place and are being followed.</li> <li>20. 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.</li> </ol>   |

#### 4. Pharmacies that dispense PALFORZIA must:

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| To become certified to dispense | <ol style="list-style-type: none"> <li>1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy.</li> <li>2. Have the authorized representative review the <a href="#">REMS Program Overview for Pharmacies</a>.</li> <li>3. Have the Authorized Representative enroll in the REMS Program by completing the <a href="#">Pharmacy Enrollment Form</a> and submitting it to the REMS Program.</li> <li>4. Train all relevant staff involved in dispensing PALFORZIA using the <a href="#">REMS Program Overview for Pharmacies</a>.</li> <li>5. For the Initial Dose Escalation: Establish processes and procedures to verify that the prescriber is certified, the patient is enrolled, and the Initial Dose Escalation is only dispensed to certified healthcare settings.</li> <li>6. For Up-Dosing prescriptions: Establish processes and procedures to verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed to the patient at a time.</li> </ol> |
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| Before dispensing the Initial Dose Escalation | 7. Verify the prescriber is certified, the patient is enrolled, and the Initial Dose Escalation is only dispensed to a certified healthcare setting through the processes and procedures established as a requirement of the REMS Program.  |
| Before dispensing all Up-Dosing prescriptions | 8. Verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed to the patient at a time through the processes and procedures established as a requirement of the REMS Program.   |
| To maintain certification to dispense         | 9. Have a new Authorized Representative enroll in the REMS Program by completing the <a href="#">Pharmacy Enrollment Form</a> if the Authorized Representative changes.   |
| At all times                                  | 10. Not dispense the Initial Dose Escalation for use outside a certified healthcare setting.<br>11. Not distribute, transfer, loan or sell PALFORZIA.<br>12. Maintain records that all processes and procedures are in place and are being followed.<br>13. 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. |

**5. Wholesalers-distributors that distribute PALFORZIA must:**

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| To be able to distribute | 1. Establish processes and procedures to ensure that PALFORZIA is distributed only to certified pharmacies and certified healthcare settings.<br>2. Train all relevant staff involved in distributing on the REMS Program requirements.   |
| At all times             | 3. Distribute only to certified pharmacies and healthcare settings.<br>4. Maintain records of PALFORZIA distribution.<br>5. 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. |

**Aimmune Therapeutics, Inc. must provide training to healthcare settings that dispense PALFORZIA.**

The training includes the following educational material: [Education Program for Healthcare Settings](#). The training must be available online and by hard copy via fax, e-mail and mail.

**Aimmune Therapeutics, Inc. must provide training to pharmacies that dispense PALFORZIA.**

The training includes the following educational materials: [REMS Program Overview for Pharmacies](#). The training must be available online and by hard copy via fax, e-mail and mail.

**To support REMS Program operations, Aimmune Therapeutics, Inc. must:**

1. Establish and maintain a REMS Program website, [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com). The REMS Program website must include the capability to complete prescriber and healthcare setting certification online, the capability to enroll patients online, verify prescriber, healthcare setting certification and patient enrollment online, the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS program website must not link back to the promotional product website(s).

2. Make the REMS Program website fully operational and all REMS Program materials available through the website and REMS Program Coordinating Center by the date PALFORZIA is first commercially distributed.
3. Establish and maintain a REMS Program Coordinating Center for REMS participants at 1-844-725-3679.
4. Establish and maintain a validated, secure database of all REMS Program participants who are enrolled and/or certified in the PALFORZIA REMS Program.
5. Ensure prescribers and healthcare settings are able to become certified in the REMS Program by fax and online.
6. Ensure pharmacies are able to become certified in the REMS Program by fax.
7. Ensure that prescribers are able to enroll patients in the REMS Program by fax and online.
8. Ensure pharmacies are able to verify patient enrollment, prescriber and healthcare setting certification by phone and online.
9. Provide the [Prescriber Enrollment Form](#), the Prescribing Information, and the [Patient Enrollment Form](#) to healthcare providers who (1) attempt to prescribe PALFORZIA and are not yet certified or (2) inquire about how to become certified.
10. Provide the [Healthcare Setting Enrollment Form](#), the [Education Program for Healthcare Settings](#) and the [Patient Enrollment Form](#) to healthcare settings that (1) attempt to dispense PALFORZIA and are not yet certified or (2) inquire about how to become certified.
11. Provide the [Pharmacy Enrollment Form](#) and the [REMS Program Overview for Pharmacies](#) to pharmacies that (1) attempt to dispense PALFORZIA and are not yet certified or (2) inquire about how to become certified.
12. Notify prescribers, healthcare settings and pharmacies within 2 business days after they become certified in the REMS Program.
13. Provide certified pharmacies access to the database of certified prescribers, healthcare settings and enrolled patients.
14. Provide authorized wholesalers-distributors access to the database of certified pharmacies and healthcare settings.
15. Provide certified prescribers and healthcare settings access to the database of certified pharmacies, authorized wholesalers-distributors and enrolled patients.

**To ensure REMS participants' compliance with the REMS Program, Aimmune Therapeutics, Inc. must:**

16. Maintain adequate records to demonstrate that REMS Program requirements have been met, including, but not limited to records of: PALFORZIA distribution and dispensing; certification of prescribers, healthcare settings, and pharmacies; enrolled patients; audits of REMS participants. These records must be readily available for FDA inspections.
17. Establish a plan for addressing noncompliance with REMS Program requirements.
18. Monitor prescribers, healthcare settings, and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including decertification.
19. Verify annually that the authorized representative's name and information correspond to the certified healthcare setting.
20. Verify annually that the authorized representative's name and information correspond to the certified pharmacy.
21. Maintain an ongoing annual audit plan of 10% (but no less than 50) certified healthcare settings and 10% (but no less than 50) certified pharmacies.

22. Audit 10% but no less than 50 certified healthcare settings no later than 120 calendar days after the healthcare setting places its first order for PALFORZIA to ensure that REMS Program processes and procedures are in place, functioning, and support the REMS Program requirements.
23. Audit 10% but no less than 50 certified pharmacies no later than 120 calendar days after the pharmacy dispenses its first prescription of PALFORZIA to ensure that REMS Program processes and procedures are in place, functioning, and support the REMS Program requirements.
24. Audit all wholesalers-distributors no later than 120 calendar days after they become authorized to distribute the drug and annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
25. Take reasonable steps to improve implementation of and compliance with the requirements in the PALFORZIA REMS Program based on monitoring and evaluation of the PALFORZIA REMS Program.

## **IV. REMS Assessment Timetable**

Aimmune Therapeutics, Inc. must submit REMS assessments at 6 months and 12 months and annually thereafter from the date of initial approval of the REMS (01/31/2020). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Aimmune Therapeutics, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

## **V. REMS Materials**

The following materials are part of the PALFORZIA REMS:

### **Enrollment Forms**

Prescriber:

1. [Prescriber Enrollment Form](#)

Patient:

2. [Patient Enrollment Form](#)

Healthcare Settings:

3. [Healthcare Setting Enrollment Form](#)

Pharmacy:

4. [Pharmacy Enrollment Form](#)

### **Training and Educational Materials**

Healthcare settings:

5. [Education Program for Healthcare Settings](#)

Pharmacy:

6. [REMS Program Overview for Pharmacies](#)

### **Other Materials**

7. [REMS Program Website](#)

# PALFORZIA REMS Prescriber 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

1. Review the PALFORZIA Prescribing Information (PI).
2. Complete and submit the *Prescriber Enrollment Form* online at [www.PALFORZIAREMS.com](http://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 prescriber of successful certification within 2 business days.

## PRESCRIBER INFORMATION

(\*indicates required field)

|   |                     |   |
|---|---------------------|---|
| First Name*:  | Last Name*:         | National Provider Identifier (NPI #)*:  |
| Credentials* (please select one):<br><input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other |                     | Specialty* (please select one):<br><input type="checkbox"/> Pediatric <input type="checkbox"/> Allergy/Immunology <input type="checkbox"/> Family Medicine <input type="checkbox"/> Other |
| Office Phone Number*:   | Office Fax Number*: | Email Address*:   |
| Practice/Facility Name*:  |                     |   |
| Address 1*:   |                     |   |
| Address 2:  |                     |   |
| City*:  | State*:             | ZIP*:   |

## OFFICE CONTACT INFORMATION

|   |   |                |
|---|---|----------------|
| First Name:   | Last Name:  |                |
| Office Phone Number: <input type="checkbox"/> Same as above | Office Fax Number: <input type="checkbox"/> Same as above | Email Address: |

**To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at  
1-844-PALFORZ (1-844-725-3679)**

## PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- o Review the PALFORZIA Prescribing Information (PI)

**Before treatment initiation, to prescribe PALFORZIA to a patient, I will:**

- o Enroll each patient in the PALFORZIA REMS by completing and submitting the *Patient Enrollment Form* and provide a completed copy of the form to the patient
- o Counsel the patient on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis
- o Assess the patient's supply of injectable epinephrine and provide prescription if necessary

**During treatment before dispensing the first dose of each Up-Dosing level, I will:**

- o Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing

**At all times:**

- o Report treatment discontinuation or transfer of care to the REMS Program



\_\_\_\_\_  
Prescriber Signature \*

\_\_\_\_\_  
Date\*



# PALFORZIA REMS Patient 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. Your healthcare provider will help you complete this form and provide you with a copy.

## PRESCRIBER INSTRUCTIONS:

1. Review the *Patient Enrollment Form* with the patient or parent/guardian and answer any questions the patient or parent/guardian has about PALFORZIA.
  2. Complete and submit the *Patient Enrollment Form* online at [www.PALFORZIAREMS.com](http://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 the form, the REMS Program will notify the prescriber of successful patient enrollment within 2 business days.

## PRESCRIBER INFORMATION

(\*indicates required field)

|                          |                 |  |
|--------------------------|-----------------|--|
| First Name*:             | Last Name*:     | National Provider Identifier (NPI #)*: |
| Practice/Facility Name*: |                 |  |
| Address 1*:              |                 |  |
| Address 2:               |                 |  |
| City*:                   | State*:         | ZIP*:                                  |
| Office Phone Number*:    | Email Address*: |  |



Signature \*

Date\*

## PATIENT INFORMATION

(\*indicates required field)

|  |   |             |                                 |   |
|--|---|-------------|---------------------------------|---|
| First Name*:   | MI:   | Last Name*: | Date of Birth*:<br>(MM/DD/YYYY) | Sex*:<br><input type="checkbox"/> Female<br><input type="checkbox"/> Male<br><input type="checkbox"/> Other |
| Address 1*:  |   | Address 2:  |                                 |   |
| City*:   | State*:   | ZIP*:       |                                 |   |
| Phone Number:  | Email Address:  |             |                                 |   |
| Parent/Guardian First Name*:   | Parent/Guardian Last Name*:   |             |                                 |   |
| Relationship to Patient*:  | Parent/Guardian Phone Number*: <input type="checkbox"/> Same as above |             |                                 |   |
| Email Address of Parent/Guardian *: <input type="checkbox"/> Same as above |   |             |                                 |   |

## PATIENT AGREEMENT

By signing this form, the patient/parent/guardian acknowledges the following:

### Before treatment begins:

- o Enroll in the PALFORZIA REMS by completing this *Patient Enrollment Form* with prescriber
- o Receive counseling on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and the first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of severe allergic reaction (anaphylaxis)

### During treatment (before the first dose of each Up-Dosing level):

- o Receive counseling from a healthcare provider on the need to be monitored for severe allergic reaction (anaphylaxis)

### During treatment (during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes):

- o Be monitored for severe allergic reaction (anaphylaxis) at the healthcare setting

### Patient/parent/guardian will:

- o Report anaphylaxis to your healthcare provider
- o Request more injectable epinephrine as needed
- o Have injectable epinephrine available for immediate use at all times
- o Avoid peanuts and foods that contain peanuts in the diet

### Patient/parent/guardian understands:

- o In order to receive PALFORZIA, patient is required to be enrolled in the REMS, and patient's information will be stored in a database of all patients who receive PALFORZIA in the United States
- o Aimmune Therapeutics, Inc., and its agents, including trusted vendors, may contact patient via phone, mail, fax, or email to support administration of the REMS

Patient or  Parent/Guardian Signature\* (please select one and sign):



Patient or Parent/Guardian Signature\*

Date\*

Printed Parent/Guardian Name (if applicable):



Phone: 1-844-PALFORZ (1-844-725-3679)

[www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com)

Fax: 1-844-285-2013

**Palförzia**  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp

# 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](http://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 #)*: |
|---------------------------|--|

|  |
|--|
| Healthcare Setting Type*:<br><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*: |
|--------|---------|-------|

|                           |  |
|---------------------------|--|
| Healthcare Setting Name*: | National Provider Identifier (NPI #)*: |
|---------------------------|--|

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|--|
| Healthcare Setting Type*:<br><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*: |
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|            |
|------------|
| Address 2: |
|------------|

|        |         |       |
|--------|---------|-------|
| City*: | State*: | ZIP*: |
|--------|---------|-------|

|                           |  |
|---------------------------|--|
| Healthcare Setting Name*: | National Provider Identifier (NPI #)*: |
|---------------------------|--|

|  |
|--|
| Healthcare Setting Type*:<br><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*: |
|--------|---------|-------|

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

|             |                     |
|-------------|---------------------|
| *Name _____ | *Phone Number _____ |
| Last        | First               |



# PALFORZIA REMS Pharmacy 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 dispense PALFORZIA, a pharmacy must designate an Authorized Representative to:

1. Review the *REMS Program Overview for Pharmacies*
2. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy
3. Complete and submit the *Pharmacy Enrollment Form* by fax to 1-844-285-2013

Upon completion of these steps, the REMS Program will notify the pharmacy of successful certification within 2 business days

## PHARMACY INFORMATION

(\*indicates required field)

|  |  |  |       |
|--|--|--|-------|
| Pharmacy Name*:  |  | National Provider Identifier (NPI #)*: |       |
| National Council for Prescription Drug Program ID (NCPDP): |  | Other Identifier:                      |       |
| Address Line 1*:   |  |  |       |
| Address Line 2:  |  |  |       |
| City*:   |  | State*:                                | ZIP*: |

## AUTHORIZED REPRESENTATIVE INFORMATION

|  |              |   |       |
|--|--------------|---|-------|
| First Name*:   |              | Last Name*:   |       |
| Role*: <input type="checkbox"/> RPH <input type="checkbox"/> PharmD <input type="checkbox"/> Other Responsible Individual <input type="checkbox"/> Other |              | Reason for Form* (please select one): <input type="checkbox"/> New Enrollment <input type="checkbox"/> New Representative |       |
| Phone Number*:   | Fax Number*: | Email Address*:   |       |
| Address 1*:  |              |   |       |
| Address 2:   |              |   |       |
| City*:   |              | State*:   | ZIP*: |

## AUTHORIZED PHARMACY REPRESENTATIVE AGREEMENT

I am the authorized representative designated by my Pharmacy to coordinate the activities of the PALFORZIA REMS. By completing, signing, and submitting this form, I agree, on behalf of myself and my Pharmacy, to comply with the following REMS requirements, **I will:**

- o Oversee implementation of and ensure my pharmacy's compliance with the PALFORZIA REMS requirements
- o Review the *REMS Program Overview for Pharmacies* and will ensure that all relevant staff involved in the dispensing of PALFORZIA are trained on the PALFORZIA REMS requirements and that a record of training is maintained
- o Train all relevant staff involved in dispensing PALFORZIA, and **establish processes and procedures** to ensure that the following take place in my pharmacy:

### Prior to dispensing the PALFORZIA Initial Dose Escalation, my pharmacy will verify:

- o The prescriber is certified
- o The patient is enrolled
- o Initial Dose Escalation is only dispensed to certified healthcare settings

### Prior to dispensing all Up-Dosing prescriptions, my pharmacy will verify:

- o The patient is enrolled
- o The prescriber is certified
- o Only one dose level is dispensed to the patient at a time

### At all times:

- o Have any new authorized representative enroll in the REMS by completing the *Pharmacy Enrollment Form*
- o Maintain records that all processes 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 dispense the Initial Dose Escalation for use outside a certified healthcare setting
- o Not distribute, transfer, loan, or sell PALFORZIA



Authorized Representative Signature \*

Date\*



Phone: 1-844-PALFORZ (1-844-725-3679)

www.PALFORZIAREMS.com

Fax: 1-844-285-2013

AIMT-REMS-USA-1006 Version Date 31Jan2020

**Palförzia**  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp

# PALFORZIA™ Education Program For Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)



***Palförzia***™  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp

# What is PALFORZIA™?

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- PALFORZIA an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.
- PALFORZIA is to be used in conjunction with a peanut-avoidant diet.
- Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- PALFORZIA is available only through a restricted program called the PALFORZIA REMS.

# PALFORZIA has a Boxed Warning

## **WARNING: ANAPHYLAXIS** **SEE PRESCRIBING INFORMATION FOR COMPLETE BOXED WARNING.**

- **PALFORZIA can cause anaphylaxis, which may be life-threatening and can occur at any time during PALFORZIA therapy.**
- **Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.**
- **Do not administer PALFORZIA to patients with uncontrolled asthma.**
- **Dose modifications may be necessary following an anaphylactic reaction.**
- **Observe patients during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes.**
- **Because of the risk of anaphylaxis, PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS.**

# What is a REMS? (Risk Evaluation and Mitigation Strategy)

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- A Risk Evaluation and Mitigation Strategy (**REMS**) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

# Goal of the PALFORZIA REMS

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- The goal of the PALFORZIA REMS is to mitigate the risk of anaphylaxis associated with PALFORZIA by:
  - Ensuring that healthcare providers who prescribe and healthcare settings that dispense and administer PALFORZIA are educated on the following:
    - the risk of anaphylaxis associated with the use of PALFORZIA
    - the Initial Dose Escalation and first dose of each Up-Dosing level must only be administered to patients in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.
  - Ensuring that the Initial Dose Escalation and the first dose of each Up-Dosing level of PALFORZIA are only dispensed and distributed to certified healthcare settings and only administered to patients in certified healthcare settings.
  - Ensuring that PALFORZIA is only dispensed and administered to patients who are informed, by enrolling in the PALFORZIA REMS Program, of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.

# Overview of PALFORZIA REMS Stakeholder Requirements

## Prescriber

- **Review** the PALFORZIA *Prescribing Information*.
- **Enroll** in the REMS by completing the *Prescriber Enrollment Form* and submitting it to the REMS.
- **Enroll each patient** in the PALFORZIA REMS by completing and submitting the *Patient Enrollment Form* and provide a completed copy of the form to the patient.
- **Counsel the patient** on the need to have injectable epinephrine available for immediate use at all times, monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.
- **Assess the patient's** supply of injectable epinephrine and provide prescription if necessary
- **Assess the patient's** tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing
- **Report** treatment discontinuation or transfer of care to the REMS Program

## Patient

- **Enroll** in the PALFORZIA REMS by completing the *Patient Enrollment Form* with a prescriber.
- **Receive counseling** from the prescriber on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and the first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of severe allergic reaction (anaphylaxis)
- **During treatment** (before the first dose of each Up-Dosing level):
  - **Receive counseling** from a healthcare provider on the need to be monitored for severe allergic reaction (anaphylaxis)
- **During treatment** (during and after administration of the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes):
  - **Be monitored** for severe allergic reaction (anaphylaxis) at the healthcare setting
- **Report anaphylaxis** to your healthcare provider
- **Request more** injectable epinephrine as needed
- Have **injectable epinephrine available** for immediate use at all times
- **Avoid peanuts** and foods that contain peanuts in the diet

# Overview of PALFORZIA REMS Stakeholder Requirements (continued)

## Healthcare Setting

- **Designate a representative** to carry out the certification process and oversee implementation and compliance with the REMS.
- Have the Authorized Representative **review the *Education Program for Healthcare Settings*** (this document).
- Have the Authorized Representative **certify** in the REMS by completing the ***Healthcare Setting Enrollment Form*** and submitting it to the REMS.
- **Train** all relevant staff
- **Establish processes and procedures** to ensure that the following take place:
  - Have a certified prescriber on-site
  - Have **healthcare provider(s) on-site** to counsel each patient, and monitor for and manage anaphylaxis
  - Be able to **manage anaphylaxis on-site**
  - Before Treatment initiation (first dose):
    - **Verify the Initial Dose Escalation** is for the enrolled patient
  - During treatment before dispensing the first dose of each Up-Dosing level:
    - Verify that the **patient is enrolled** in the REMS
    - Have a **healthcare provider counsel the patient** on the need to be monitored for anaphylaxis
    - **Verify** that the dose, as determined by the certified prescriber, is dispensed from the **Office Dose Kit**
    - Verify that the **patient has injectable epinephrine**
  - During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level
    - Assess the patient for anaphylaxis for at least 60 minutes
- Have any **new Authorized Representative** enroll in the REMS by completing the ***Healthcare Setting Enrollment Form***
- **Maintain records** of dispensing and all processes and procedures
- Comply with **audits**
- **Do not distribute, transfer, loan, or sell PALFORZIA**

## Pharmacy

- **Designate a representative** to carry out the certification process and oversee implementation and compliance with the REMS.
- Have the Authorized Representative **review the *REMS Program Overview for Pharmacies***.
- Have the Authorized Representative **certify** in the REMS by completing the ***Pharmacy Enrollment Form*** and submitting it to the REMS.
- **Train** all relevant staff associated with PALFORZIA.
- **Support** electronic data exchanges and communication with the PALFORZIA REMS system.
- Prior to dispensing the PALFORZIA Initial Dose Escalation, my pharmacy will verify:
  - The prescriber is certified.
  - The patient is enrolled.
  - Initial Dose Escalation is only dispensed to certified healthcare settings.
- Prior to dispensing all Up-Dosing prescriptions, my pharmacy will verify:
  - The patient is enrolled.
  - The prescriber is certified.
  - Only one dose level is dispensed to the patient at a time.

# How to Become a Certified Healthcare Setting

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- 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](http://www.PALFORZIAREMS.com) or by fax to 1-844-285-2013
- Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

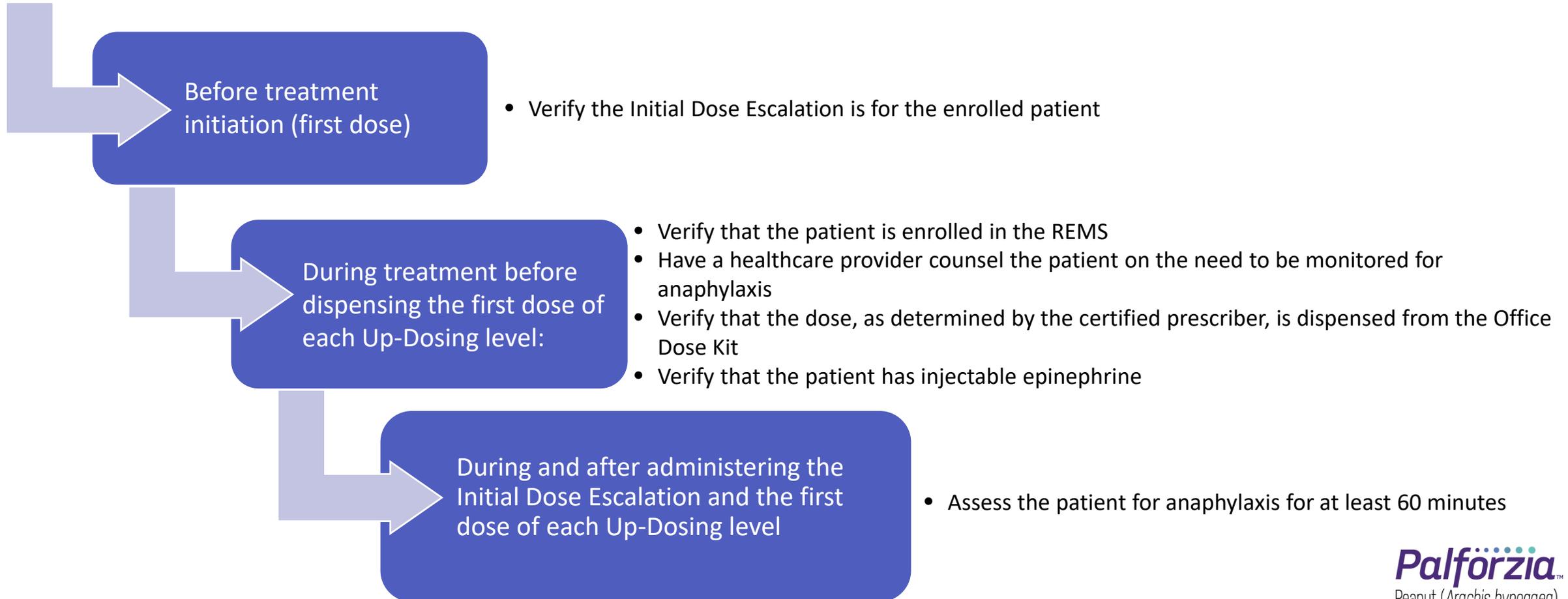
# Healthcare Setting Requirements

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

# Healthcare Setting Requirements

- Establish processes and procedures to ensure that the following take place:



# Healthcare Setting Requirements

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- At All Times:
  - Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
  - Maintain records of dispensing and that all processes and procedures are in place and are being followed
  - 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
  - Not distribute, transfer, loan, or sell PALFORZIA

# Adverse Event Reporting

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- To report negative side effects:
  - Contact Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566), or
  - FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or
  - Call FDA at 1-800-FDA-1088 (1-800-332-1088)

# Ordering Instructions

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To order patient-specific PALFORZIA,  
contact a certified pharmacy



To order an Office Dose Kit  
contact a certified distributor



Visit the [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) website to obtain a list  
of pharmacies that are certified to dispense PALFORZIA



Call the REMS Program at 1-844-PALFORZ (1-844-725-3679)  
to obtain a list of  
wholesaler-distributors that are certified to supply  
PALFORZIA

# PALFORZIA REMS Resources

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- For more information about the PALFORZIA REMS, visit [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) or call the REMS Program at 1-844-PALFORZ (1-844-725-3679)

Please see PALFORZIA Prescribing Information, including Boxed Warning and Medication Guide,  
for additional Important Safety Information

# THANK YOU



***Palforzia***<sup>™</sup>  
Peanut (*Arachis hypogaea*)  
Allergen Powder-dnfp

# PALFORZIA REMS Program Overview for Pharmacies

## What is the PALFORZIA Risk Evaluation and Mitigation Strategy (REMS)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. PALFORZIA is available only through a restricted program called the PALFORZIA REMS because of the risk of anaphylaxis.

## What are the PALFORZIA REMS requirements?

- ✓ Healthcare providers who prescribe PALFORZIA™ must be certified with the program by enrolling
- ✓ Only certified pharmacies and healthcare settings may dispense PALFORZIA
- ✓ The Initial Dose Escalation and first dose of each Up-Dosing level are only administered to patients in certified healthcare settings
- ✓ Patients must be informed of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis
- ✓ Only enrolled patients can receive PALFORZIA

## How can a pharmacy become enrolled in the PALFORZIA REMS?

In order to enroll and become certified, the Pharmacy must:

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the pharmacy, including:

- Overseeing implementation of and ensuring pharmacy's compliance with the PALFORZIA REMS requirements
- Reviewing the *REMS Program Overview for Pharmacies* (this document) and ensuring that all relevant staff involved in the dispensing of PALFORZIA are trained on the PALFORZIA REMS requirements and that a record of training is maintained
- Training all relevant staff involved in dispensing PALFORZIA, and **establishing processes and procedures** to ensure that the following take place in pharmacy:

**Prior to dispensing the PALFORZIA Initial Dose Escalation, pharmacy will verify:**

- The prescriber is certified
- The patient is enrolled
- Initial Dose Escalation is only dispensed to certified healthcare settings

**Prior to dispensing all Up-Dosing prescriptions, pharmacy will verify:**

- The patient is enrolled
- The prescriber is certified
- Only one dose level is dispensed to the patient at a time

**At all times:**

- Having any new authorized representative enroll in the REMS by completing the *Pharmacy Enrollment Form*
- Maintaining records that all processes are in place and are being followed
- Complying 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
- Not dispensing the Initial Dose Escalation for use outside a certified healthcare setting
- Not distributing, transferring, loaning, or selling PALFORZIA

PALFORZIA is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

**Visit [www.PALFORZIAREMS.com](http://www.PALFORZIAREMS.com) to begin enrollment and for additional information.**

**You may also contact the PALFORZIA REMS at 1-844-PALFORZ (1-844-725-3679)**





## Welcome to the PALFORZIA REMS (Risk Evaluation and Mitigation Strategy) Program

The PALFORZIA REMS (Risk Evaluation and Mitigation Strategy) Program is a safety program that manages the risk of anaphylaxis associated with PALFORZIA™. The PALFORZIA REMS Program is required by the Food and Drug Administration (FDA) to ensure the potential benefits of PALFORZIA outweigh its risks.



### Healthcare Settings

Healthcare settings must become certified in the PALFORZIA REMS Program to administer PALFORZIA.

[LEARN ABOUT HEALTHCARE SETTING CERTIFICATION.](#)

[LEARN MORE](#)



### Prescribers

Prescribers must become certified in the PALFORZIA REMS Program to prescribe PALFORZIA.

[LEARN ABOUT PRESCRIBER CERTIFICATION.](#)

[LEARN MORE](#)



### Pharmacies

Pharmacies must become certified in the PALFORZIA REMS Program to dispense PALFORZIA.

[LEARN ABOUT PHARMACY CERTIFICATION.](#)

[LEARN MORE](#)



### Patients

Patients who are prescribed PALFORZIA must be enrolled in the PALFORZIA REMS Program.

[LEARN ABOUT PATIENT ENROLLMENT.](#)

[LEARN MORE](#)



## GOALS

The goal of the PALFORZIA REMS Program is to mitigate the risk of anaphylaxis associated with PALFORZIA by:

- Ensuring that healthcare providers who prescribe and healthcare settings that dispense and administer PALFORZIA are educated on the following:
  - the risk of anaphylaxis associated with the use of PALFORZIA
  - the Initial Dose Escalation and first dose of each Up-Dosing level must only be administered to patients in a healthcare setting equipped to monitor patients, and to identify and manage anaphylaxis.
- Ensuring that the Initial Dose Escalation and the first dose of each Up-Dosing level of PALFORZIA are only dispensed and distributed to certified healthcare settings and only administered to patients in certified healthcare settings.
- Ensuring that PALFORZIA is only dispensed and administered to patients who are informed, by enrolling in the PALFORZIA REMS Program, of the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.

If you have questions about the PALFORZIA REMS Program or need help with certification or enrollment, call 1-844-PALFORZ (1-844-725-3679) Monday-Friday, 8:00am – 8:00pm ET

To learn more about the serious risks associated with PALFORZIA, please refer to the [Prescribing Information](#) including Boxed Warning and the [Medication Guide](#).

## INDICATION

PALFORZIA is indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

To report side effects please contact Aimune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566) or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088).

[Privacy Policy](#) [Terms of Use](#)

## Healthcare Setting Overview

PALFORZIA is only available through the PALFORZIA REMS Program. In order for a healthcare setting to administer PALFORZIA, they must become certified.

### TO BECOME CERTIFIED IN THE PALFORZIA REMS PROGRAM, HEALTHCARE SETTINGS MUST:

1

**DESIGNATE AN AUTHORIZED REPRESENTATIVE** to review the [Education Program for Healthcare Settings](#)

2

**HAVE THE AUTHORIZED REPRESENTATIVE** carry out the certification process and oversee implementation and compliance with the REMS Program

- A healthcare provider(s) must be on-site to counsel the patient and monitor for and manage anaphylaxis
- Have a certified prescriber on-site
- Be able to manage anaphylaxis on-site
- Train all relevant staff involved in dispensing and administering PALFORZIA

3

**COMPLETE AND SUBMIT** the *Healthcare Setting Enrollment Form* to the PALFORZIA REMS Program

- [Online](#)
- [By fax at 1-844-285-2013](#)

Healthcare settings will be notified of successful certification in the PALFORZIA REMS Program within 2 business days.

### THE HEALTHCARE SETTING MUST ESTABLISH PROCESSES AND PROCEDURES TO ENSURE THAT THE FOLLOWING TAKE PLACE:

Before treatment initiation, the healthcare setting will:

1

Verify the Initial Dose Escalation is for the enrolled patient

During treatment, before dispensing the first dose of each Up-Dosing level, the healthcare setting will:

1

Verify that the patient is enrolled in the REMS

2

Have a healthcare provider counsel the patient on the need to be monitored for anaphylaxis

3

Verify that the dose, as determined by the certified prescriber, is dispensed from the Office Dose Kit

4

Verify that the patient has injectable epinephrine

During and after administering the Initial Dose Escalation and the first dose of each Up-Dosing level, for at least 60 minutes, the healthcare setting will:

1

Assess the patient for anaphylaxis



## 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* below 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.

(\* indicates required field)

### HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)

CONTINUE

### AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name

\*Last Name

\*Role

- Physician
  Physician Assistant
  Nurse Practitioner
  Pharmacist
  Nurse
  Other Responsible Individual Designated by Healthcare Setting
  Practice Manager
  Administrator

\*Reason for Form (please select one)

- New Enrollment  
 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:

- Oversee implementation of and ensure my healthcare setting's compliance with the PALFORZIA REMS requirements
- Review the *Education Program for Healthcare Settings*
- Have a certified prescriber on-site
- Have healthcare provider(s) on-site to counsel each patient, and monitor for and manage anaphylaxis
- Be able to manage anaphylaxis on-site
- 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):

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

#### DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL:

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

#### DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSING LEVEL:

- Assess the patient for anaphylaxis for at least 60 minutes

#### AT ALL TIMES:

- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
- Maintain records of dispensing and that all processes and procedures are in place and are being followed
- 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
- Not distribute, transfer, loan, or sell PALFORZIA

\*Authorized Representative Signature

CANCEL

CONTINUE





# 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* below 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.

(\* indicates required field)

## HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)

If the healthcare setting name/address do not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZ (1-844-725-3679).

\*Healthcare Setting Name

\*Healthcare Setting Type  
 Independent Practice  Private Group Practice  Outpatient Clinic  Hospital Ambulatory Clinic  Other

\*Address 1  Address 2

\*City  \*State  \*ZIP

If you are certifying more than one healthcare setting location for which the Authorized Representative is responsible, click on "Add Healthcare Setting" below and provide the information for each site below.

+ ADD HEALTHCARE SETTING

## AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name  \*Last Name

\*Role  
 Physician  Physician Assistant  Nurse Practitioner  Pharmacist  Nurse  
 Other Responsible Individual Designated by Healthcare Setting  Practice Manager  Administrator

\*Reason for Form (please select one)  
 New Enrollment  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:**
- Oversee implementation of and ensure my healthcare setting's compliance with the PALFORZIA REMS requirements
  - Review the *Education Program for Healthcare Settings*
  - Have a certified prescriber on-site
  - Have healthcare provider(s) on-site to counsel each patient, and monitor for and manage anaphylaxis
  - Be able to manage anaphylaxis on-site
  - 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):**
- Verify the Initial Dose Escalation is for the enrolled patient
- DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL:**
- Verify that the patient is enrolled in the REMS
  - Have a healthcare provider counsel the patient on the need to be monitored for anaphylaxis
  - Verify that the dose, as determined by the certified prescriber, is dispensed from the Office Dose Kit
  - Verify that the patient has injectable epinephrine
- DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSING LEVEL:**
- Assess the patient for anaphylaxis for at least 60 minutes
- AT ALL TIMES:**
- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
  - Maintain records of dispensing and that all processes and procedures are in place and are being followed
  - 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
  - Not distribute, transfer, loan, or sell PALFORZIA

\*Authorized Representative Signature





## 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* below 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.

(\* indicates required field)

### HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)

1234567890

If the healthcare setting name/address do not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZ (1-844-725-3679).

\*Healthcare Setting Name

ABC Healthcare Setting

\*Healthcare Setting Type

Independent Practice  Private Group Practice  Outpatient Clinic  Hospital Ambulatory Clinic  Other

\*Address 1

123 Main Street

Address 2

\*City

Philadelphia

\*State

PA

\*ZIP

99999

\*National Provider Identifier (NPI#)

CONTINUE

If you are certifying more than one healthcare setting location for which the Authorized Representative is responsible, click on "Add Healthcare Setting" below and provide the information for each site below.

+ ADD HEALTHCARE SETTING

### AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name

\*Last Name

\*Role

Physician  Physician Assistant  Nurse Practitioner  Pharmacist  Nurse  
 Other Responsible Individual Designated by Healthcare Setting  Practice Manager  Administrator

\*Reason for Form (please select one)

New Enrollment  New Authorized Representative

\*Phone Number

\*Fax Number

\*Email Address

\*Address 1

Address 2

\*City

\*State

-- Please Select --

\*ZIP

### HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT

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- Be able to manage anaphylaxis on-site
- 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):

- Verify the Initial Dose Escalation is for the enrolled patient

#### DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL:

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

#### DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSING LEVEL:

- Assess the patient for anaphylaxis for at least 60 minutes

#### AT ALL TIMES:

- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
- Maintain records of dispensing and that all processes and procedures are in place and are being followed
- 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
- Not distribute, transfer, loan, or sell PALFORZIA

\*Authorized Representative Signature

CANCEL

CONTINUE





## PALFORZIA REMS Healthcare Setting Enrollment Form

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(\* indicates required field)

### HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)

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\*Healthcare Setting Name

\*Healthcare Setting Type

Independent Practice
  Private Group Practice
  Outpatient Clinic
  Hospital Ambulatory Clinic
  Other

\*Address 1

Address 2

\*City

\*State

\*ZIP

\*National Provider Identifier (NPI#)

If the healthcare setting name/address do not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZ (1-844-725-3679).

\*Healthcare Setting Name

\*Healthcare Setting Type

Independent Practice
  Private Group Practice
  Outpatient Clinic
  Hospital Ambulatory Clinic
  Other

\*Address 1

Address 2

\*City

\*State

\*ZIP

**X REMOVE HEALTHCARE SETTING**

If you are certifying more than one healthcare setting location for which the Authorized Representative is responsible, click on "Add Healthcare Setting" below and provide the information for each site below.

**+ ADD HEALTHCARE SETTING**

### AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name

\*Last Name

\*Role

Physician
  Physician Assistant
  Nurse Practitioner
  Pharmacist
  Nurse
  Other Responsible Individual Designated by Healthcare Setting
  Practice Manager
  Administrator

\*Reason for Form (please select one)

New Enrollment
  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:

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- Have a certified prescriber on-site
- Have healthcare provider(s) on-site to counsel each patient, and monitor for and manage anaphylaxis
- Be able to manage anaphylaxis on-site
- 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):

- Verify the Initial Dose Escalation is for the enrolled patient

#### DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL:

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

#### DURING AND AFTER ADMINISTERING THE INITIAL DOSE ESCALATION AND THE FIRST DOSE OF EACH UP-DOSING LEVEL:

- Assess the patient for anaphylaxis for at least 60 minutes

#### AT ALL TIMES:

- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
- Maintain records of dispensing and that all processes and procedures are in place and are being followed
- 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
- Not distribute, transfer, loan, or sell PALFORZIA

\*Authorized Representative Signature

CANCEL

CONTINUE



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## PALFORZIA REMS Healthcare Setting Certification Successful

You have successfully completed and submitted the *Healthcare Setting Enrollment Form*.

Confirmation of your certification has been sent to the email address provided.

To report side effects please contact  
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)  
or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
or call 1-800-FDA-1088 (1-800-332-1088).

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## Prescriber Overview

PALFORZIA is only available through the PALFORZIA REMS Program. In order for a prescriber to prescribe PALFORZIA, they must become certified.

### TO BECOME CERTIFIED IN THE PALFORZIA REMS PROGRAM, PRESCRIBERS MUST:

1

**REVIEW** the PALFORZIA [Prescribing Information](#)

2

**COMPLETE AND SUBMIT** the *Prescriber Enrollment Form* to the PALFORZIA REMS Program

- [Online](#)
- [By fax at 1-844-285-2013](#)

Prescribers will be notified of successful certification in the PALFORZIA REMS Program within 2 business days.

### HOW DO I ENROLL A PATIENT IN THE PALFORZIA REMS PROGRAM?

1

**COMPLETE** the PALFORZIA *Patient Enrollment Form* with each patient prior to administering PALFORZIA:

- [Online](#)
- [By fax at 1-844-285-2013](#)
  - [Patient Enrollment Form \(English\)](#)
  - [Patient Enrollment Form \(Spanish\)](#)

### ADMINISTRATION REQUIREMENTS:

Before treatment initiation, the prescriber will:

1

Enroll the patient

2

Provide the patient with a completed copy of the *Patient Enrollment Form*

3

Counsel the patient on:

- the need to have injectable epinephrine available for immediate use at all times
- the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level
- the need for continued peanut avoidance in the diet
- how to recognize the signs and symptoms of anaphylaxis

4

Assess the patient's supply of injectable epinephrine and provide prescription if necessary

During treatment and before dispensing the first dose of each Up-Dosing level, the prescriber will:

1

Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing

At all times, the prescriber will:

1

Report patient treatment discontinuation or transfer of care



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## PALFORZIA REMS Prescriber 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

1

**REVIEW** the PALFORZIA Prescribing Information (PI).

2

**COMPLETE AND SUBMIT** the *Prescriber Enrollment Form* below 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 prescriber of successful certification within 2 business days.

(\* indicates required field)

### PRESCRIBER INFORMATION

\*National Provider Identifier (NPI#)

CONTINUE

### OFFICE CONTACT INFORMATION

First Name

Last Name

Office Phone Number - Same as above

Office Fax Number - Same as above

Email Address

Office Phone Number

Office Fax Number



To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZ (1-844-725-3679)

### PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- Review the PALFORZIA Prescribing Information (PI)

#### BEFORE TREATMENT INITIATION, TO PRESCRIBE PALFORZIA TO A PATIENT, I WILL:

- Enroll each patient in the PALFORZIA REMS by completing and submitting the *Patient Enrollment Form* and provide a completed copy of the form to the patient.
- Counsel the patient on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis
- Assess the patient's supply of injectable epinephrine and provide prescription if necessary

#### DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL, I WILL:

- Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing

#### AT ALL TIMES:

- Report treatment discontinuation or transfer of care to the REMS Program

\*Prescriber Signature

CANCEL

CONTINUE

To report side effects please contact  
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)  
or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
or call 1-800-FDA-1088 (1-800-332-1088).

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## PALFORZIA REMS Prescriber Enrollment Form

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### INSTRUCTIONS

1

**REVIEW** the PALFORZIA Prescribing Information (PI).

2

**COMPLETE AND SUBMIT** the *Prescriber Enrollment Form* below 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 prescriber of successful certification within 2 business days.

(\* indicates required field)

### PRESCRIBER INFORMATION

\*National Provider Identifier (NPI#)

1234567890

If the prescriber name/address do not match what is displayed below, please contact the PALFORZIA REMS Call Center at 1-844-PALFORZ (1-844-725-3679).

\*First Name

John

\*Last Name

Smith

\*Credentials (please select one)

MD  DO  NP  PA  Other

\*Specialty (please select one)

Pediatric  Allergy/Immunology  Family Medicine  Other

\*Office Phone Number

\*Office Fax Number

\*Email Address

\*Practice/Facility Name

\*Address 1

123 Main Street

Address 2

\*City

Philadelphia

\*State

PA

\*ZIP

99999

### OFFICE CONTACT INFORMATION

First Name

Last Name

Office Phone Number - Same as above

Office Fax Number - Same as above

Email Address

Office Phone Number

Office Fax Number

To provide additional Office Contacts please contact the PALFORZIA REMS Coordinating Center at 1-844-PALFORZ (1-844-725-3679)

### PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- Review the PALFORZIA Prescribing Information (PI)

#### BEFORE TREATMENT INITIATION, TO PRESCRIBE PALFORZIA TO A PATIENT, I WILL:

- Enroll each patient in the PALFORZIA REMS by completing and submitting the *Patient Enrollment Form* and provide a completed copy of the form to the patient.
- Counsel the patient on the need to have injectable epinephrine available for immediate use at all times, the need for monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis
- Assess the patient's supply of injectable epinephrine and provide prescription if necessary

#### DURING TREATMENT BEFORE DISPENSING THE FIRST DOSE OF EACH UP-DOSING LEVEL, I WILL:

- Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the Up-Dosing

#### AT ALL TIMES:

- Report treatment discontinuation or transfer of care to the REMS Program

\*Prescriber Signature

CANCEL

CONTINUE





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## PALFORZIA REMS Prescriber Enrollment Successful

You have successfully completed and submitted the *Prescriber Enrollment Form*.

Confirmation of your certification has been sent to the email address provided.

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Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)  
or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
or call 1-800-FDA-1088 (1-800-332-1088).

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## Pharmacies

Dispensing of PALFORZIA is limited to contracted pharmacies that will be certified in the PALFORZIA REMS Program.

### TO BECOME CERTIFIED IN THE PALFORZIA REMS PROGRAM, PHARMACIES MUST:

1

**DESIGNATE AN AUTHORIZED REPRESENTATIVE** to review the [REMS Program Overview for Pharmacies](#)

2

**HAVE THE AUTHORIZED REPRESENTATIVE** carry out the certification process and oversee implementation and compliance with the REMS Program

3

**COMPLETE AND SUBMIT** the *Pharmacy Enrollment Form* to the PALFORZIA REMS Program

- [By fax at 1-844-285-2013](#)

Pharmacies will be notified of certification in the PALFORZIA REMS Program within 2 business days.

### DISPENSING REQUIREMENTS:

1

**PRIOR TO DISPENSING THE PALFORZIA INITIAL DOSE ESCALATION**, my pharmacy will verify:

- The prescriber is certified
- The patient is enrolled
- Initial Dose Escalation is only dispensed to certified healthcare settings

2

**PRIOR TO DISPENSING ALL UP-DOSING PRESCRIPTIONS**, my pharmacy will verify:

- The patient is enrolled
- The prescriber is certified
- Only one dose level is dispensed to the patient at a time

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## Patients

PALFORZIA is available only through the PALFORZIA REMS Program. For a patient to receive PALFORZIA the prescriber must enroll the patient in the PALFORZIA REMS Program.

### HOW DO I BECOME ENROLLED IN THE PALFORZIA REMS PROGRAM?

1

**DISCUSS THE BENEFITS AND RISKS** of PALFORZIA with your doctor.

2

**ASK YOUR DOCTOR** any questions you have about taking PALFORZIA and about the PALFORZIA REMS Program.

3

**MAKE SURE** you understand:

- How to enroll and take part in the PALFORZIA REMS
- The benefits and risks of PALFORZIA
- That you must have injectable epinephrine available at all times
- That you must avoid peanuts or peanut containing foods in the diet
- That you know the signs and symptoms of severe allergic reaction (anaphylaxis) and to tell your doctor if you have any of these signs or symptoms
- You will need to receive certain doses at your doctor's office
- You will need to be monitored after doses received at your doctor's office for at least 60 minutes

4

**TOGETHER WITH YOUR DOCTOR,** complete and sign the *Patient Enrollment Form*.

- [Patient Enrollment Form \(English\)](#)
- [Patient Enrollment Form \(Spanish\)](#)

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## Resources



### Resources for Healthcare Settings

- [PALFORZIA REMS Education Program for Healthcare Settings](#)
- [PALFORZIA REMS Healthcare Setting Enrollment Form](#)



### Resources for Prescribers

- [PALFORZIA REMS Prescriber Enrollment Form](#)
- [PALFORZIA REMS Patient Enrollment Form - English](#)
- [PALFORZIA REMS Patient Enrollment Form - Spanish](#)



### Resources for Pharmacies

- [PALFORZIA REMS Program Overview for Pharmacies](#)
- [PALFORZIA REMS Pharmacy Enrollment Form](#)



### Resources for Patients

- [Medication Guide](#)
- [PALFORZIA REMS Patient Enrollment Form - English](#)
- [PALFORZIA REMS Patient Enrollment Form - Spanish](#)

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## Certified Participant Locator

For a list of authorized wholesalers-distributors, please contact the PALFORZIA REMS Program at 1-844-PALFORZ (1-844-725-3679).

\* Please select a certified participant to locate

Prescriber/Healthcare Setting  Pharmacy

To report side effects please contact  
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)  
or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
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# Certified Participant Locator

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\*Please select a certified participant to locate

- Prescriber/Healthcare Setting
- Pharmacy

\* Zip Code:

\* Search Radius:

SEARCH

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\*Please select a certified participant to locate

Prescriber/Healthcare Setting  Pharmacy

\* Zip Code:

\* Search Radius:

-- Please Select --

-- Please Select --

Within 25 miles

Within 50 miles

Within 100 miles

SEARCH

To report side effects please contact  
Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566)  
or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
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# Certified Participant Locator

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\*Please select a certified participant to locate

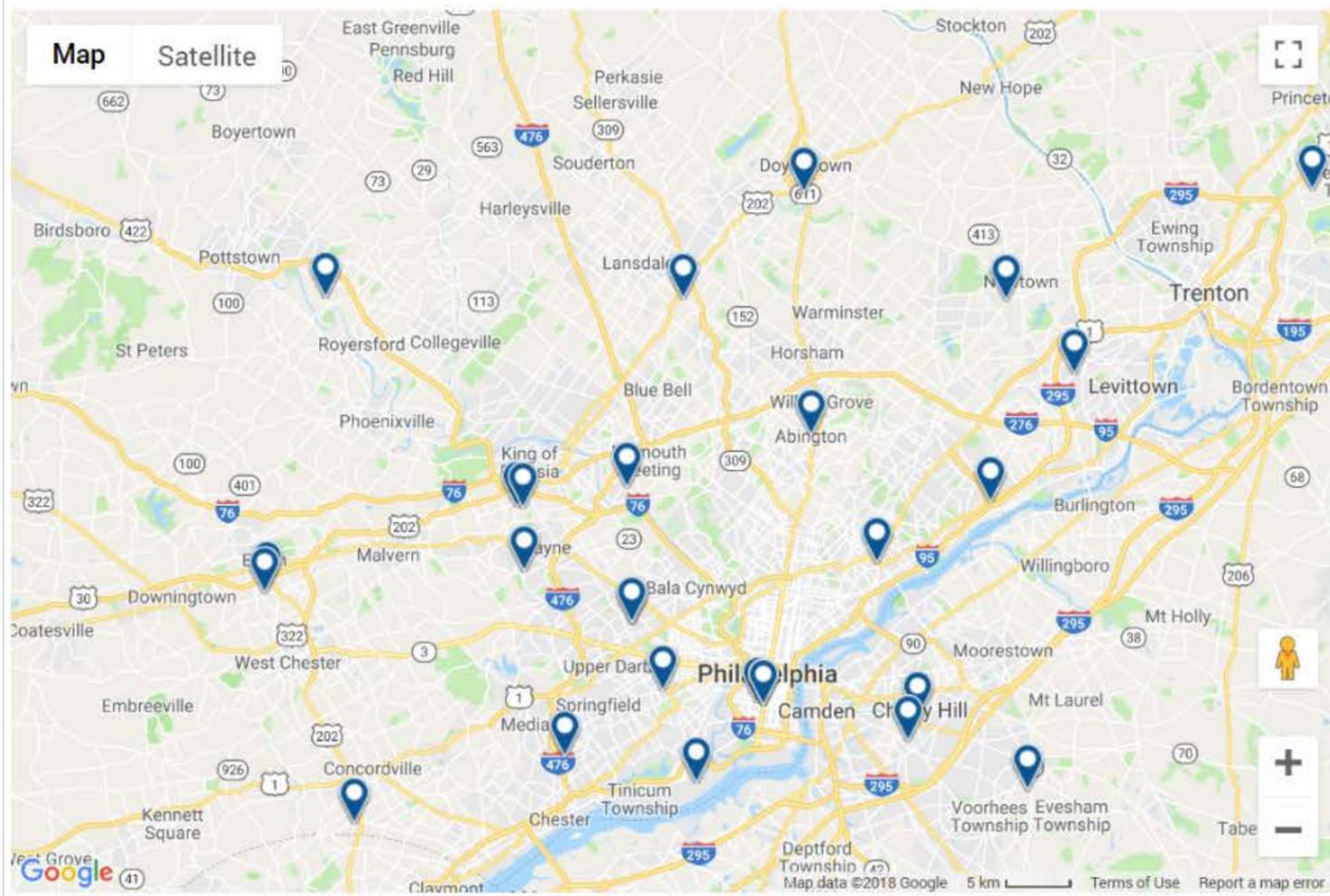
Prescriber/Healthcare Setting  Pharmacy

Certified Prescribers **Certified Healthcare Settings**

Search filters and map controls area.

\*Zip Code:  \*Search Radius:

SEARCH



|  |                            |
|--|----------------------------|
| <b>PRESCRIBER NAME</b>                             | 75.1 miles                 |
| 100 Main St<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>PRESCRIBER NAME</b>                             | 75.6 miles                 |
| 100 Main St<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>PRESCRIBER NAME</b>                             | 75.6 miles                 |
| 100 Main St<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>PRESCRIBER NAME</b>                             | 75.6 miles                 |
| 100 Main St<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>PRESCRIBER NAME</b>                             | 76.2 miles                 |
| 100 Main St<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>PRESCRIBER NAME</b>                             | 76.6 miles                 |

To report side effects please contact Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566) or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088).

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## Certified Participant Locator

For a list of authorized wholesalers-distributors, please contact the PALFORZIA REMS Program at 1-844-PALFORZ (1-844-725-3679).

\*Please select a certified participant to locate

Prescriber/Healthcare Setting  Pharmacy

Certified Prescribers

Certified Healthcare Settings

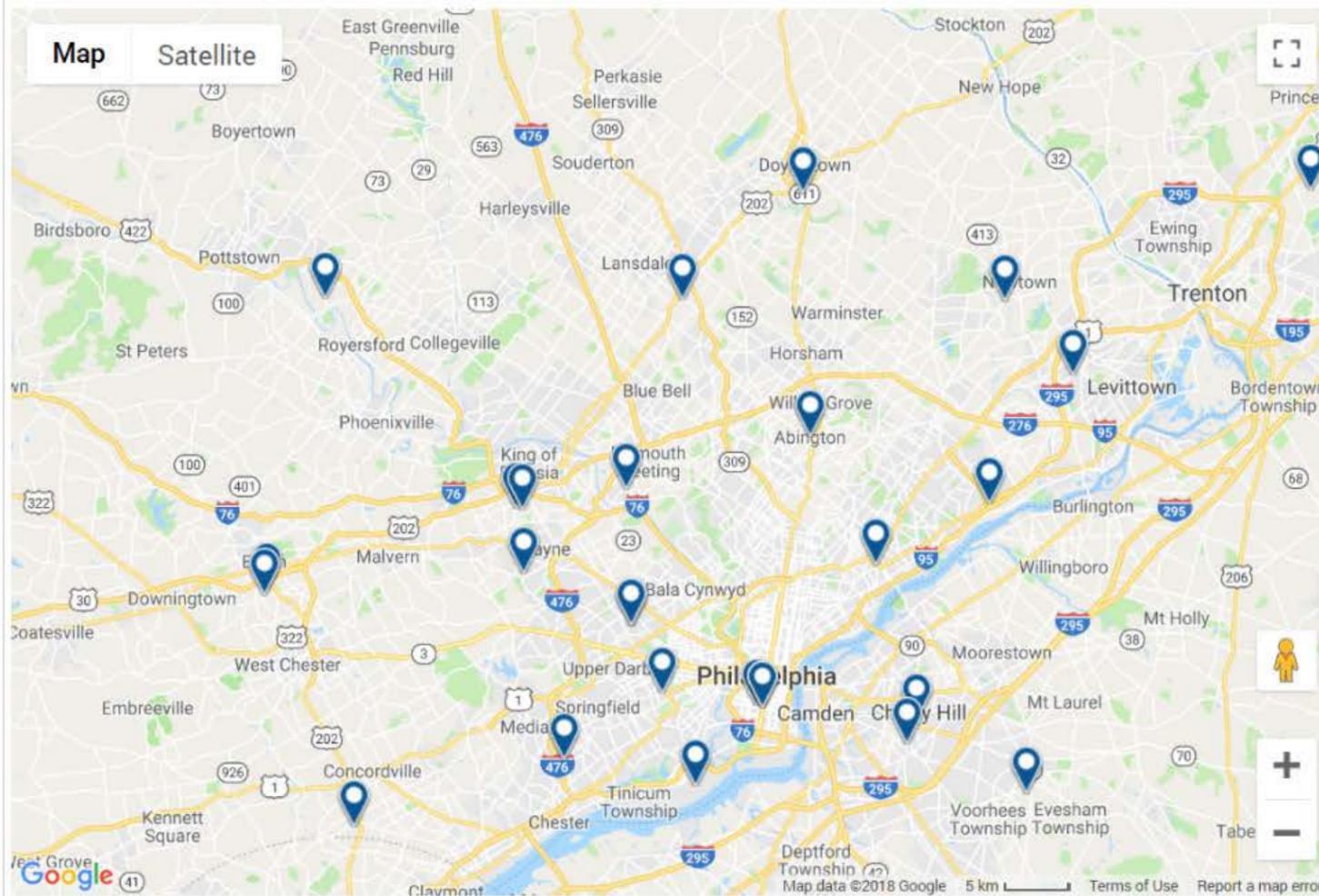
\*Zip Code:

12345

\*Search Radius:

Within 25 miles

SEARCH



|   |                            |
|---|----------------------------|
| <b>HEALTHCARE SETTING NAME</b>                                      | 75.6 miles                 |
| 920 Harvest Drive<br>Blue Bell, PA 19422<br>555 555-1212            | <a href="#">Directions</a> |
| <b>HEALTHCARE SETTING NAME</b>                                      | 75.6 miles                 |
| 920 Harvest Drive<br>STE 200<br>Blue Bell, PA 19422<br>555 555-1212 | <a href="#">Directions</a> |
| <b>HEALTHCARE SETTING NAME</b>                                      | 75.6 miles                 |
| 920 Harvest Drive<br>#200<br>Blue Bell, PA 19422<br>555 555-1212    | <a href="#">Directions</a> |
| <b>HEALTHCARE SETTING NAME</b>                                      | 76.6 miles                 |
| 2703 Aspen Cir<br>Blue Bell, PA 19422<br>555 555-1212               | <a href="#">Directions</a> |
| <b>HEALTHCARE SETTING NAME</b>                                      | 77.1 miles                 |
| eolmbni<br>AKJIWpR<br>KwKww, PA 19101<br>555 555 1212               | <a href="#">Directions</a> |

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or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
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\*Please select a certified participant to locate

- Prescriber/Healthcare Setting
- Pharmacy

## Certified Pharmacies

| Pharmacy Name | Phone Number |
|---------------|--------------|
| ABC Pharmacy  | 555 555-1212 |

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## Login



Login is available to certified prescribers to enroll patients, certified healthcare setting users to verify patient enrollment and certified pharmacy users to verify patient, prescriber and healthcare setting enrollment prior to dispensing PALFORZIA.

**LOGIN**

[Forgot Username](#)

To report side effects please contact  
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or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)  
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## Contact Us



### Phone

1-844-PALFORZ (1-844-725-3679)



### Fax

1-844-285-2013



### Hours of Operation

Monday - Friday  
8:00 AM - 8:00 PM  
Eastern Time

For more information on PALFORZIA, please read the [Medication Guide](#).

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