



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 or call 1-800-FDA-1088 (1-800-332-1088).

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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#)

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

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INSTRUCTIONS

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1	2	3
REVIEW the <i>Education Program for Healthcare Settings</i> .	CARRY OUT THE CERTIFICATION PROCESS and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting.	COMPLETE AND SUBMIT the <i>Healthcare Setting Enrollment Form</i> 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

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I WILL:

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- 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

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INSTRUCTIONS

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- 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

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- 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

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(* 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#)

9999999999

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

XYZ Medical Center

*Healthcare Setting Type

Independent Practice Private Group Practice Outpatient Clinic Hospital Ambulatory Clinic Other

*Address 1

999 Broadway

Address 2

*City

Philadelphia

*State

PA

*ZIP

99999

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

-- Please Select --

*ZIP

HEALTHCARE SETTING AUTHORIZED REPRESENTATIVE AGREEMENT

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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
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

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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#)

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

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or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

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Aimmune Therapeutics, Inc.



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1

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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#)

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

*Last Name

*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

Address 2

*City

*State

*ZIP

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

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- 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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or FDA at www.fda.gov/medwatch
or call 1-800-FDA-1088 (1-800-332-1088).

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Aimmune Therapeutics, Inc.



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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

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

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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

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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:

12345

* Search Radius:

-- Please Select --

-- Please Select --

Within 25 miles

Within 50 miles

Within 100 miles

SEARCH

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- Prescriber/Healthcare Setting
- Pharmacy

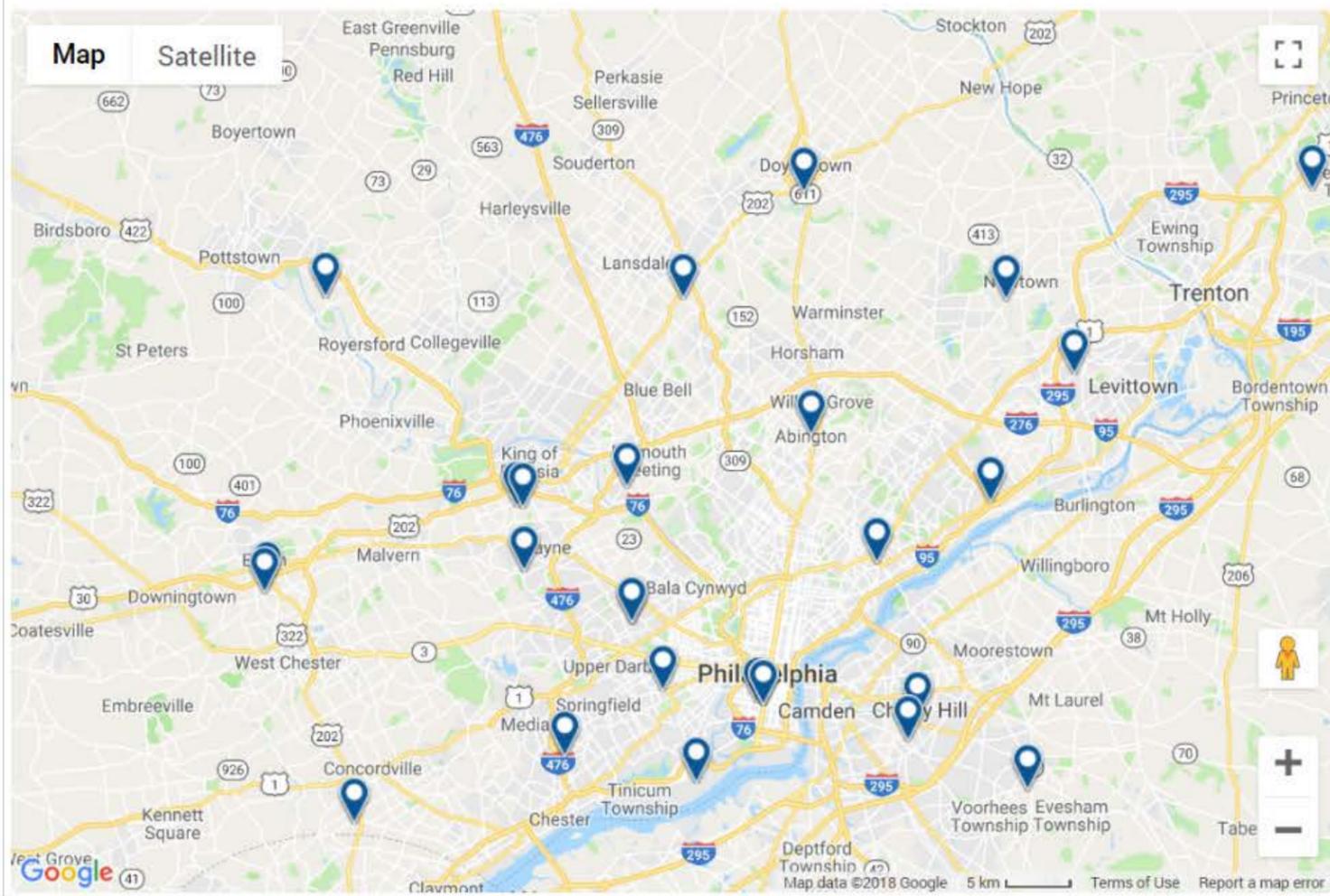
Certified Prescribers **Certified Healthcare Settings**

Search filters and map area

*Zip Code:

*Search Radius:

SEARCH



PRESCRIBER NAME	75.1 miles
100 Main St Blue Bell, PA 19422	Directions
555 555-1212	
PRESCRIBER NAME	75.6 miles
100 Main St Blue Bell, PA 19422	Directions
555 555-1212	
PRESCRIBER NAME	75.6 miles
100 Main St Blue Bell, PA 19422	Directions
555 555-1212	
PRESCRIBER NAME	75.6 miles
100 Main St Blue Bell, PA 19422	Directions
555 555-1212	
PRESCRIBER NAME	76.2 miles
100 Main St Blue Bell, PA 19422	Directions
555 555-1212	
PRESCRIBER NAME	76.6 miles

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*Please select a certified participant to locate

Prescriber/Healthcare Setting Pharmacy

Certified Prescribers

Certified Healthcare Settings

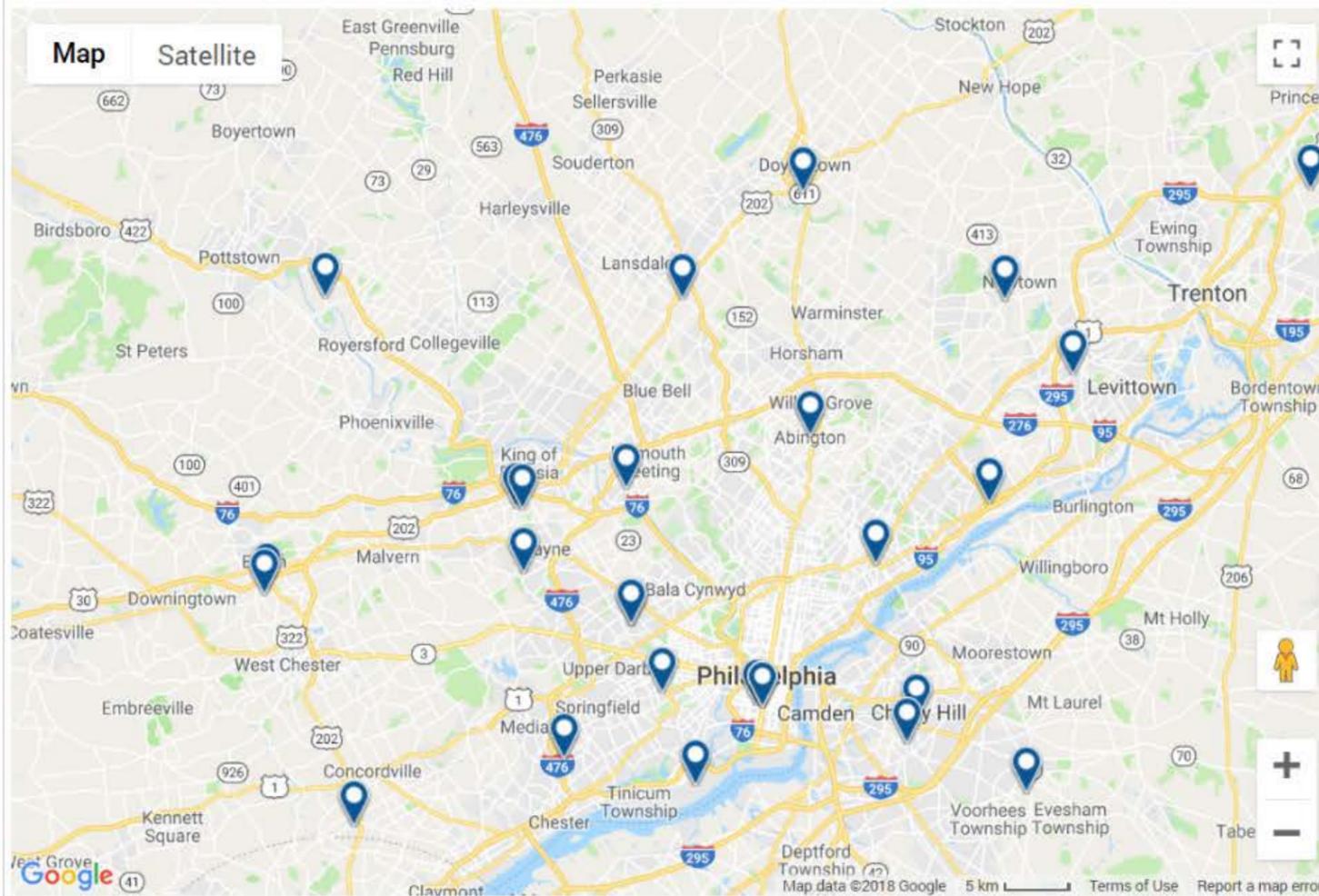
*Zip Code:

12345

*Search Radius:

Within 25 miles

SEARCH



HEALTHCARE SETTING NAME	75.6 miles
920 Harvest Drive Blue Bell, PA 19422 555 555-1212	Directions
HEALTHCARE SETTING NAME	75.6 miles
920 Harvest Drive STE 200 Blue Bell, PA 19422 555 555-1212	Directions
HEALTHCARE SETTING NAME	75.6 miles
920 Harvest Drive #200 Blue Bell, PA 19422 555 555-1212	Directions
HEALTHCARE SETTING NAME	76.6 miles
2703 Aspen Cir Blue Bell, PA 19422 555 555-1212	Directions
HEALTHCARE SETTING NAME	77.1 miles
eolmbni AKJIWpR KwKww, PA 19101 555 555-1212	Directions

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- 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](#)

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Phone

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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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