Risk Evaluation and Mitigation Strategy (REMS) Document
PALFORZIA [Peanut (*Arachis hypogaea*) Allergen Powder-dnfp] REMS Program

I. Administrative Information

Risk: Anaphylaxis (also called anaphylactic reaction)
Application Number: BLA 125696
Application Holder: Aimmune Therapeutics, Inc.
Initial REMS Approval: 01/2020
Most Recent REMS Update: 07/2024

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 new 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 new 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 new 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:

1. Healthcare providers who prescribe PALFORZIA must:	
To become certified to prescribe	1. Review the PALFORZIA Prescribing Information. 2. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.

Before treatment initiation (first dose)	3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS Program. Provide a completed copy of the form to the patient. 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 new Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis. 5. Assess the patient's supply of injectable epinephrine and provide prescription if necessary.
During treatment; before dispensing the first dose of each new Up-Dosing level	6. Assess the patient's tolerability of the previous dosing level and appropriateness of continuing the new Up-Dosing.
During treatment; before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use	7. Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level.
During treatment; before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use	8. Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level.
At all times	9. Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form. 10. Report treatment discontinuation or transfer of care to the REMS Program.
2. Patients who are prescribed PALFORZIA:	
Before treatment initiation	1. Enroll in the REMS Program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS Program. 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 new Up-Dosing level, the need for continued peanut avoidance in the diet, and how to recognize the signs and symptoms of anaphylaxis.
During treatment, before the first dose of each new Up-Dosing level	3. Receive counseling from a healthcare provider on the need for monitoring for anaphylaxis.
During treatment, during and after administration of the Initial Dose Escalation and the first dose of each new Up-Dosing level, for at least 60 minutes	4. Be monitored for anaphylaxis at the healthcare setting.

At all times	5. Report anaphylaxis to your healthcare provider. 6. Inform your healthcare provider if you need more injectable epinephrine. 7. Have injectable epinephrine available for immediate use. 8. Adhere to the safe use conditions: avoid peanuts and foods that contain peanuts.
3. Healthcare settings that dispense PALFORZIA must:	
To become certified to dispense	1. Have healthcare provider(s) on-site to monitor for and manage anaphylaxis. 2. Have a certified prescriber on-site. 3. Be able to manage anaphylaxis on-site. 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. 5. Have the authorized representative review the Education Program for Healthcare Settings. 6. Have the authorized representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form and submitting it to the REMS Program. 7. Train all relevant staff involved in dispensing and administering PALFORZIA using the Education Program for Healthcare Settings. 8. Establish processes and procedures to verify the Initial Dose Escalation is prescribed to initiate treatment. 9. Establish processes and procedures to verify the dose, as determined by the certified prescriber, from either the Office Dose Kit or the Daily Dose Pack is dispensed to enrolled patients for the first dose of each new Up-Dosing level. 10. 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 new Up-Dosing level. 11. Establish processes and procedures to verify the patient has injectable epinephrine before the first dose of each new Up-Dosing level. 12. Establish processes and procedures to verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level before dispensing a Daily Dose Pack directly to the patient for home use.
Before administering (first dose)	13. Verify the Initial Dose Escalation is for the enrolled patient.
During treatment; before the first dose of each new Up-Dosing level	14. Verify that the patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS Program. 15. Counsel the patient on the need for monitoring for anaphylaxis. 16. Verify that the dose, as determined by the certified prescriber, is dispensed from either the Office Dose Kit or the Daily Dose Pack through the processes and procedures established as a requirement of the REMS Program. 17. Verify that the patient has injectable epinephrine through the processes and procedures established as a requirement of the REMS Program.

During and after administering the Initial Dose Escalation and the first dose of each new Up-Dosing level, for at least 60 minutes	18. Assess the patient for anaphylaxis through the processes and procedures established as a requirement of the REMS Program.
During treatment; before dispensing a Daily Dose Pack directly to the patient for home use	19. Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level through processes and procedures established as a requirement of the REMS Program.
To maintain certification to dispense	20. Have a new Authorized Representative enroll in the REMS Program by completing the Healthcare Setting Enrollment Form if the authorized representative changes.
At all times	21. Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the Anaphylaxis Adverse Event Reporting Form. 22. Not distribute, transfer, loan or sell PALFORZIA. 23. Maintain records of dispensing and that all processes and procedures are in place and are being followed. 24. Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient 25. 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.
4. Pharmacies that dispense PALFORZIA must:	
To become certified to dispense	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. 2. Have the authorized representative review the REMS Program Overview for Pharmacies. 3. Have the Authorized Representative enroll in the REMS Program by completing the Pharmacy Enrollment Form and submitting it to the REMS Program. 4. Train all relevant staff involved in dispensing PALFORZIA using the REMS Program Overview for Pharmacies. 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. 6. For all Up-Dosing (Daily Dose Pack) prescriptions: Establish processes and procedures to verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed at a time. 7. For Daily Dose Packs dispensed directly to a patient by shipping it to them for home use: Establish processes and procedures to verify with the prescriber or healthcare setting and document the patient was monitored and previously tolerated the first dose of each new Up-Dosing level.

Before dispensing the Initial Dose Escalation	8. 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 (Daily Dose Pack) prescriptions	9. Verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed at a time through the processes and procedures established as a requirement of the REMS Program.
Before dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use	10. Verify with the prescriber or healthcare setting and document that the patient was monitored and previously tolerated the first dose of each new Up-Dosing level through the processes and procedures established as a requirement of the REMS Program.
To maintain certification to dispense	11. Have a new Authorized Representative enroll in the REMS Program by completing the Pharmacy Enrollment Form if the Authorized Representative changes.
At all times	12. Not dispense the Initial Dose Escalation for use outside a certified healthcare setting. 13. Not dispense a Daily Dose Pack for the first dose of each new Up-Dosing level for use outside a certified healthcare setting. 14. Not distribute, transfer, loan or sell PALFORZIA. 15. Maintain records that all processes and procedures are in place and are being followed. 16. 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:	
To be able to distribute	1. Establish processes and procedures to ensure that PALFORZIA is distributed only to certified pharmacies and certified healthcare settings. 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. 4. Maintain records of PALFORZIA distribution. 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. 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, report anaphylaxis adverse events, and 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 prescribers and healthcare providers are able to report any adverse events of anaphylaxis by fax and mail using the Anaphylaxis Adverse Event Reporting Form, and online.
9. Ensure pharmacies are able to verify patient enrollment, prescriber and healthcare setting certification by phone and online.
10. Provide the Prescriber Enrollment Form, the Prescribing Information, the Patient Enrollment Form, and the Anaphylaxis Adverse Event Reporting Form to healthcare providers who (1) attempt to prescribe PALFORZIA and are not yet certified or (2) inquire about how to become certified.
11. Provide the Healthcare Setting Enrollment Form, the Education Program for Healthcare Settings, the Patient Enrollment Form, and the Anaphylaxis Adverse Event Reporting Form to healthcare settings that (1) attempt to dispense PALFORZIA and are not yet certified or (2) inquire about how to become certified.
12. 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.
13. Notify prescribers, healthcare settings and pharmacies within 2 business days after they become certified in the REMS Program.
14. Provide certified pharmacies access to the database of certified prescribers, healthcare settings and enrolled patients.
15. Provide authorized wholesalers-distributors access to the database of certified pharmacies and healthcare settings.
16. 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:

17. 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; documentation of completed Anaphylaxis Adverse Event Reporting Forms; audits of REMS participants. These records must be readily available for FDA inspections.

18. Establish a plan for addressing noncompliance with REMS Program requirements.
19. 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.
20. Verify annually that the authorized representative's name and information correspond to the certified healthcare setting.
21. Verify annually that the authorized representative's name and information correspond to the certified pharmacy.
22. 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.
23. 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.
24. 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.
25. 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.
26. 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

Wholesaler-Distributor:

5. Wholesaler-Distributor Enrollment Form

Training and Educational Materials

Healthcare settings:

6. Education Program for Healthcare Settings

Pharmacy:

7. REMS Program Overview for Pharmacies
8. REMS Specialty Pharmacy Training

Patient Care Forms

9. Anaphylaxis Adverse Event Reporting Form

Other Materials

10. REMS Program Website

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1 and consists of the following elements:

1. Elements to Assure Safe Use:

- Healthcare providers have particular experience or training, or are specially certified under 5051(f)(3)(A).
- Pharmacies, practitioners, or health care settings that dispense PALFORZIA are specially certified under 505-1(f)(3)(B).
- PALFORZIA is dispensed to patients only in certain health care settings under 505-1(f)(3)(C).
- PALFORZIA is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D).
- Each patient using PALFORZIA is subject to certain monitoring under 5051(f)(3)(E).

2. Implementation System

3. Timetable for Submission of Assessments

Version Date 07/24

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 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): ☐ 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:

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 new 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

During treatment before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use, I will:

- Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

During treatment before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use, I will:

- Verify the patient was monitored and previously tolerated the first dose of the Up-Dosing level

At all times:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- Report treatment discontinuation or transfer of care to the REMS Program

_____ **Prescriber Signature ***

_____ **Date***

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Phone: 1-844-PALFORZ (1-844-725-3679) **www.PALFORZIAREMS.com** **Fax: 1-844-285-2013**

Palforzia® Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

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 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*: (MM/DD/YYYY)	Sex*: ☐ Female ☐ Male ☐ 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*: ☐ Same as above		
Email Address of Parent/Guardian *: ☐ Same as above				

PATIENT AGREEMENT

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

Before treatment begins:
- Enroll in the PALFORZIA REMS by completing this *Patient Enrollment Form* with prescriber
- 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 new 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 new 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 new Up-Dosing level, for at least 60 minutes)*:
- Be monitored for severe allergic reaction (anaphylaxis) at the healthcare setting

Patient/parent/guardian will:
- 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

Patient/parent/guardian understands:
- 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
- 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):

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Phone: 1-844-PALFORZ (1-844-725-3679) **www.PALFORZIAREMS.com** **Fax: 1-844-285-2013**

Palforzia® Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

Version Date 05/24

PALFORZIA REMS Healthcare Setting Enrollment Form

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

INSTRUCTIONS

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

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

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

HEALTHCARE SETTING INFORMATION

(*indicates required field)

Healthcare Setting Name*:

National Provider Identifier (NPI #)*:

Healthcare Setting Type*: ☐ 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, check this box and provide the information for each site below.

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 new 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 either the Office Dose Kit or the Daily Dose Pack
  - 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 new Up-Dosing level:

- Assess the patient for anaphylaxis for at least 60 minutes

During treatment before dispensing a Daily Dose Pack directly to the patient for home use:

- Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

At all times:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- 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
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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 *: ______________________ 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*: ☐ Independent Practice ☐ Private Group Practice ☐ Outpatient Clinic ☐ Hospital Ambulatory Clinic ☐ Other		
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

Healthcare Setting Name*:		National Provider Identifier (NPI #)*:
Healthcare Setting Type*: ☐ Independent Practice ☐ Private Group Practice ☐ Outpatient Clinic ☐ Hospital Ambulatory Clinic ☐ Other		
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

Healthcare Setting Name*:		National Provider Identifier (NPI #)*:
Healthcare Setting Type*: ☐ Independent Practice ☐ Private Group Practice ☐ Outpatient Clinic ☐ Hospital Ambulatory Clinic ☐ Other		
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

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

***Name** ______________________ (Last) ______________________ (First) ***Phone Number** ______________________

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*: ☐ RPH ☐ PharmD ☐ Other Responsible Individual ☐ Other	Reason for Form* (please select one): ☐ New Enrollment ☐ 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**:

- Oversee implementation of and ensure my pharmacy's compliance with the PALFORZIA REMS requirements
- 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
- 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:

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

Prior to dispensing all Up-Dosing (Daily Dose Pack) prescriptions, my pharmacy will verify:

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

Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, my pharmacy will verify with the prescriber or healthcare setting and document:

- The patient was monitored and previously tolerated the first dose of each new Up-Dosing level

At all times:

- Have any new authorized representative enroll in the REMS by completing the *Pharmacy Enrollment Form*
- Maintain records that all processes 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
- <u>Not</u> dispense the Initial Dose Escalation for use outside a certified healthcare setting
- <u>Not</u> dispense a Daily Dose Pack for the first dose of an Up-Dosing level for use outside a certified healthcare setting.
- <u>Not</u> distribute, transfer, loan, or sell PALFORZIA

Authorized Representative Signature * **Date***

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Phone: 1-844-PALFORZ (1-844-725-3679) **www.PALFORZIAREMS.com** **Fax: 1-844-285-2013**

Version Date 05/24

PALFORZIA REMS Wholesaler-Distributor 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 enrolled in the PALFORZIA REMS Program and distribute PALFORZIA, a wholesaler-distributor must designate an Authorized Representative to:

1. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the wholesaler-distributor.
2. Complete and submit the *Wholesaler-Distributor Enrollment Form* by fax to 1-844-285-2013.

Upon completion of these steps, the REMS Program will notify the wholesaler-distributor of successful enrollment within 2 business days.

WHOLESALER-DISTRIBUTOR INFORMATION

(*indicates required field)

Wholesaler-Distributor Name*:		
National Provider Identifier (NPI #)*:	Other Identifier:	
Address Line 1*:		
Address Line 2:		
City*:	State*:	ZIP*:

AUTHORIZED REPRESENTATIVE INFORMATION

First Name*:	Last Name*:	
Role:	Position:	
Phone Number*:	Fax Number*:	Email Address*:
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

WHOLESALER-DISTRIBUTOR AGREEMENT

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

- Oversee implementation of and ensure my wholesaler-distributor is in compliance with the PALFORZIA REMS requirements
- Train all relevant staff involved in distributing PALFORZIA on the REMS Program requirements and establish processes and procedures to ensure that the following take place:
  - Ensure PALFORZIA is distributed only to certified pharmacies and certified healthcare settings
- Maintain records of distribution
- 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

Authorized Representative Signature *: _____ **Date*:** _____

PALFORZIA® Education Program For Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)

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What is PALFORZIA®?

- 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 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year 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.

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PALFORZIA has a Boxed Warning

WARNING: ANAPHYLAXIS

SEE PRESCRIBING INFORMATION FOR COMPLETE BOXED WARNING.

- **PALFORZIA can cause anaphylaxis (also called anaphylactic reaction), 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 new 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.**

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

- 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.

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Goal of the PALFORZIA REMS

- 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 new 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 new 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 new Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize the signs and symptoms of anaphylaxis.

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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 new 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
- During treatment, **before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use:**
  - **Verify the patient was monitored and previously tolerated** the first dose of the new Up-Dosing level
- During treatment, **before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use:**
  - **Verify the patient was monitored and previously tolerated** the first dose of new the Up-Dosing level
- **Report anaphylaxis** including suspected cases managed as anaphylaxis to the REMS Program using the ***Anaphylaxis Adverse Event Reporting Form***
- **Report** treatment discontinuation or transfer of care to the REMS Program

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Overview of PALFORZIA REMS Stakeholder Requirements (continued)

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 new 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 Initial Dose Escalation and the first dose of each new 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 new 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

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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 new 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 either the **Office Dose Kit or the Daily Dose Pack**
    - Verify that the **patient has injectable epinephrine**
  - During and after administering the Initial Dose Escalation and the first dose of each new Up-Dosing level
    - Assess the patient for anaphylaxis for at least 60 minutes
  - During treatment before dispensing a Daily Dose Pack directly to the patient for home use:
    - **Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level**
- **Report anaphylaxis** including suspected cases managed as anaphylaxis to the REMS Program using the ***Anaphylaxis Adverse Event Reporting Form***
- Have any **new Authorized Representative** enroll in the REMS by completing the *Healthcare Setting Enrollment Form*
- **Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient**
- **Maintain records** of dispensing and all processes and procedures
- Comply with **audits**
- **Do not distribute, transfer, loan, or sell PALFORZIA**

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Overview of PALFORZIA REMS Stakeholder Requirements (continued)

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 (Daily Dose Pack) prescriptions, my pharmacy will verify:
  - The patient is enrolled.
  - The prescriber is certified.
  - Only one dose level is dispensed at a time.
- Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, my pharmacy will verify with the prescriber or healthcare setting and document:
  - The patient was monitored and previously tolerated the first dose of the new Up-Dosing level

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How to Become a Certified Healthcare Setting

- To become certified in the PALFORZIA REMS Program and administer PALFORZIA, a healthcare setting (HCS) must designate an Authorized Representative to:
  1. Review the *Education Program for Healthcare Settings*
  2. Carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting
  3. Complete and submit the *Healthcare Setting Enrollment Form*
     - Online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013
- Upon completion of these steps, the REMS Program will notify the healthcare setting of successful certification within 2 business days.

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Healthcare Setting Requirements

- 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

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Healthcare Setting Requirements

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

Before treatment initiation (first dose)

- Verify the Initial Dose Escalation is for the enrolled patient

During treatment before dispensing the first dose of each new 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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

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

- Assess the patient for anaphylaxis for at least 60 minutes

During treatment before dispensing a Daily Dose Pack directly to the patient for home use:

- Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

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Initial Dose Escalation (IDE) Dosing Configuration

- **IDE Ages 1-3 years Contains 4 Doses: Levels A, B, C, D**

Table 1a: Dosing Configuration for Initial Dose Escalation Ages 1-3 years (Single Day Dose Escalation)

Dose Level	Total Dose	Dose Configuration
A	0.5 mg	One 0.5 mg capsule
B	1 mg	One 1 mg capsule
C	1.5 mg	One 0.5 mg capsule; One 1 mg capsule
D	3 mg	Three 1 mg capsules

Initial Dose Escalation supplied as a single card consisting of 4 blisters containing a total of 7 capsules.

- **IDE Dose Levels for Patients Ages 1 through 3**:
  - 4 doses (Levels A-D)
    - 0.5mg, 1mg, 1.5mg, and 3mg ONLY

- **IDE Ages 4-17 years Contains 5 Doses: Levels A, B, C, D, E**

Table 1b: Dosing Configuration for Initial Dose Escalation Ages 4-17 years (Single Day Dose Escalation)

Dose Level	Total Dose	Dose Configuration
A	0.5 mg	One 0.5 mg capsule
B	1 mg	One 1 mg capsule
C	1.5 mg	One 0.5 mg capsule; One 1 mg capsule
D	3 mg	Three 1 mg capsules
E	6 mg	Six 1 mg capsules

Initial Dose Escalation supplied as a single card consisting of 5 blisters containing a total of 13 capsules.

- **IDE Dose Levels for Patients Ages 4 through 17:**
  - 5 doses (Levels A-E)
    - 0.5mg, 1mg, 1.5mg, 3mg, and 6mg

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Up-Dosing Daily Dosing Configuration

Table 2: Daily Dosing Configuration for Up-Dosing

Dose Level	Total Daily Dose	Daily Dose Configuration	Dose Duration (weeks)	Patient age (years)
0	1 mg	One 1 mg capsule	2	1 - 3
1	3 mg	Three 1 mg capsules	2	1 - 17
2	6 mg	Six 1 mg capsules	2	1 - 17
3	12 mg	Two 1 mg capsules; One 10 mg capsule	2	1 - 17
4	20 mg	One 20 mg capsule	2	1 - 17
5	40 mg	Two 20 mg capsules	2	1 - 17
6	80 mg	Four 20 mg capsules	2	1 - 17
7	120 mg	One 20 mg capsule; One 100 mg capsule	2	1 - 17
8	160 mg	Three 20 mg capsules; One 100 mg capsule	2	1 - 17
9	200 mg	Two 100 mg capsules	2	1 - 17
10	240 mg	Two 20 mg capsules; Two 100 mg capsules	2	1 - 17
11	300 mg	One 300 mg sachet	2	1 - 17

- Patients ages 1-3 years start Up-Dosing at Dose Level 0 (1 mg)
- Patients ages 4-17 years start Up-Dosing at Dose Level 1 (3 mg)

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Healthcare Setting Requirements

- At All Times:
  - Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
  - Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
  - 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

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Adverse Event Reporting

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- Report any other type of adverse event, by contacting:
  - Aimmune Therapeutics, Inc. at 1-833-AIM2KNO (1-833-246-2566), or
  - FDA at www.fda.gov/medwatch, or
  - Call FDA at 1-800-FDA-1088 (1-800-332-1088)

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Ordering Instructions

To order patient-specific PALFORZIA (Initial Dose Escalation, Daily Dose Pack), contact a certified pharmacy

To order an Office Dose Kit contact a certified distributor

Visit the 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

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PALFORZIA REMS Resources

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

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

THANK YOU

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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 new 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 new 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 (Daily Dose Pack) prescriptions, pharmacy will verify:

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

Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, pharmacy will verify with the prescriber or healthcare setting and document:

- The patient was monitored and previously tolerated the first dose of each new Up-Dosing level

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* dispensing a Daily Dose Pack for the first dose of each new Up-Dosing level 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 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older.

Visit 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)

PALFORZIA REMS Program Specialty Pharmacy Training

Risk Evaluation and Mitigation Strategy (REMS)

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Indication

- 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 1 through 17 years
  - Up-Dosing and Maintenance may be continued in patients 1 year 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

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Important Safety Information

WARNING: ANAPHYLAXIS

- **PALFORZIA can cause anaphylaxis (also called anaphylactic reaction), 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 new 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.**

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Important Safety Information

Contraindications

- PALFORZIA is contraindicated in patients with uncontrolled asthma, or with a history of eosinophilic esophagitis and other eosinophilic gastrointestinal disease.

WARNINGS AND PRECAUTIONS

Anaphylaxis

- PALFORZIA can cause anaphylaxis, which may be life threatening. PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS because of the risk of anaphylaxis. Only prescribers, healthcare settings, pharmacies, and patients certified and enrolled in the REMS Program can prescribe, receive, dispense or administer PALFORZIA.
- Anaphylaxis has been reported during all phases of PALFORZIA dosing, including Maintenance and in subjects who have undergone recommended Up-Dosing and dose modification procedures.
- Do not initiate PALFORZIA treatment in a patient who has had severe or life-threatening anaphylaxis within the previous 60 days. PALFORZIA may not be suitable for patients with certain medical conditions that may reduce the ability to survive anaphylaxis, including but not limited to markedly compromised lung function, severe mast cell disorder, or cardiovascular disease. In addition, PALFORZIA may not be suitable for patients taking medications that can inhibit or potentiate the effects of epinephrine.

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Anaphylaxis (cont'd)

- All Initial Dose Escalation doses and the first dose of each new Up-Dosing level must be administered under observation in a certified health care setting.
- Patients may be more likely to experience allergic reactions following PALFORZIA administration in the presence of cofactors such as exercise, hot water exposure, intercurrent illness (e.g., viral infection), or fasting. Other potential cofactors may include menstruation, sleep deprivation, nonsteroidal anti-inflammatory drug use, or uncontrolled asthma. Patients should be proactively counseled about the potential for the increased risk of anaphylaxis in the presence of these cofactors. If possible, adjust the time of dosing to avoid these cofactors. If it is not possible to avoid these cofactors, consider withholding PALFORZIA temporarily.

Asthma

- Uncontrolled asthma is a risk factor for a serious outcome, including death, in anaphylaxis. Ensure patients with asthma have their asthma under control prior to initiation of PALFORZIA.
- PALFORZIA should be temporarily withheld if the patient is experiencing an acute asthma exacerbation. Following resolution of the exacerbation, resumption of PALFORZIA should be undertaken cautiously. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of PALFORZIA.

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Important Safety Information (cont'd)

WARNINGS AND PRECAUTIONS

Eosinophilic Gastrointestinal Disease

- Discontinue PALFORZIA and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastrointestinal symptoms, including dysphagia, vomiting, nausea, gastroesophageal reflux, chest pain, or abdominal pain.

Gastrointestinal Adverse Reactions

- Gastrointestinal adverse reactions were commonly reported in PALFORZIA-treated subjects, and dose modification should be considered for patients who report these reactions. For severe or persistent gastrointestinal symptoms consider a diagnosis of eosinophilic esophagitis.

ADVERSE REACTIONS

- The most common adverse reactions reported in subjects ages 1 through 3 years treated with PALFORZIA (incidence ≥ 5%) are:
  - Cough, sneezing, rhinitis, nasal congestion, throat irritation, wheezing, abdominal pain, vomiting, diarrhea, oral pruritis, oropharyngeal pain, urticaria, rash, pruritis, perioral dermatitis.
- The most common adverse reactions reported in subjects ages 4 through 17 years treated with PALFORZIA (incidence ≥ 5% and at least 5 percentage points greater than that reported in subjects with placebo) are:
  - Abdominal pain, vomiting, nausea, oral pruritus, oral paresthesia, throat irritation, cough, rhinorrhea, sneezing, throat tightness, wheezing, dyspnea, pruritus, urticaria, anaphylactic reaction, and ear pruritus.

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REMS Overview

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What is the PALFORZIA REMS?

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

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PALFORZIA REMS Goals

- 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 new 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 new 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 new Up-Dosing level, the need for continued dietary peanut avoidance, and how to recognize signs and symptoms of anaphylaxis.

Key Stakeholders:

Healthcare Setting

Prescribers

Patient Prescribed PALFORZIA

Pharmacies

Wholesalers-Distributors

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Overview of PALFORZIA REMS Stakeholder Requirements

Wholesaler-Distributor

- **Designate a representative** to oversee compliance with the REMS Program
- **Train** all relevant staff
- Ensure PALFORZIA is **distributed** only to certified pharmacies and healthcare settings
- Maintain **records** of distribution
- Comply with **audits**

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Overview of PALFORZIA REMS Stakeholder Requirements

Pharmacy

- **Designate a representative** to oversee compliance with the REMS Program
- Review the ***REMS Program Overview for Pharmacies***
- Complete the ***Pharmacy Enrollment Form***
- **Train** all relevant staff
- **Support** electronic data exchanges and communication with the PALFORZIA REMS system
- Prior to dispensing the **Initial Dose Escalation** 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** (Daily Dose Pack) verify:*
  - The patient is enrolled
  - The prescriber is certified
  - Only one dose level is dispensed at a time
- Prior to dispensing a Daily Dose Pack directly to a patient by shipping it to them for home use, verify with the prescriber or healthcare setting and document:
  - The patient was monitored and previously tolerated the first dose of the new Up-Dosing level
- Maintain records of dispensing and all processes and procedures
- Comply with audits
- Not dispense the Initial Dose Escalation for use outside a certified healthcare setting
- Not dispense a Daily Dose Pack for the first dose of a new Up-Dosing level for use outside a certified healthcare setting
- Not distribute, transfer, loan, or sell PALFORZIA

If the Up-Dosing Daily Dose Pack or Maintenance is shipped to a healthcare setting instead of the patient, the healthcare setting must be certified in the REMS

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Overview of PALFORZIA REMS Stakeholder Requirements

Healthcare Setting

- **Designate a representative** to oversee compliance with the REMS Program
- Review the ***Education Program for Healthcare Settings***
- Complete the ***Healthcare Setting Enrollment Form***
- **Train** all relevant staff
- 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 new 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 either the **Office Dose Kit or the Daily Dose Pack**
  - Verify that the **patient has injectable epinephrine**
- During and after administering the Initial Dose Escalation and the first dose of each new Up-Dosing level
  - **Assess the patient for anaphylaxis** for at least 60 minutes
- During treatment before dispensing a Daily Dose Pack directly to the patient for home use:
  - **Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level**
- **Report anaphylaxis** including suspected cases managed as anaphylaxis to the REMS Program using the ***Anaphylaxis Adverse Event Reporting Form***
- **Maintain records** of dispensing and all processes and procedures
- **Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient**
- Comply with **audits**
- **Do not distribute, transfer, loan or sell PALFORZIA**

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Overview of PALFORZIA REMS Stakeholder Requirements

Prescriber

- **Review** the PALFORZIA Prescribing Information
- **Enroll** in the REMS Program by completing the *Prescriber Enrollment Form*
- **Enroll each patient** by completing the *Patient Enrollment Form*
- **Before treatment initiation,** to prescribe PALFORZIA to a patient**:**
  - **Counsel the patient** on:
    - having injectable epinephrine at all times
    - monitoring with IDE & first dose of each new Up-Dosing
    - continued peanut avoidance in the diet
    - how to recognize anaphylaxis
  - Assess the patient's **supply of injectable epinephrine** and provide prescription if necessary
- During treatment, **before dispensing the first dose of each new Up-Dosing level**:
  - Assess the patient's **tolerability** of the previous dosing level and appropriateness of continuing the Up-Dosing
- During treatment, **before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use:**
  - **Verify the patient was monitored and previously tolerated** the first dose of the new Up-Dosing level
- During treatment, **before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use:**
  - **Verify the patient was monitored and previously tolerated** the first dose of the new Up-Dosing level
- **Report anaphylaxis** including suspected cases managed as anaphylaxis to the REMS Program using the ***Anaphylaxis Adverse Event Reporting Form***
- **Report** treatment discontinuation or transfer of care

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Overview of PALFORZIA REMS Stakeholder Requirements

Patient

- **Enroll** in the REMS Program with a prescriber
- **Before treatment begins, receive counseling** from the prescriber on:
  - having injectable epinephrine at all times
  - monitoring after Initial Dose Escalation and each new Up-Dosing
  - continued peanut avoidance in the diet
  - how to recognize anaphylaxis
- **During treatment** (before the first dose of each new 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 new Up-Dosing level, for at least 60 minutes):
  - **Be monitored** for severe allergic reaction (anaphylaxis) at the healthcare setting
- **Report anaphylaxis** to their 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

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How to Become a Certified Pharmacy

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

Review ***REMS Program Overview for Pharmacies***

Enroll in the REMS Program by completing and submitting the ***Pharmacy Enrollment Form*** by fax to **1-844-285-2013**

Train all relevant staff involved in dispensing PALFORZIA using the *REMS Program Overview for Pharmacies*

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.

For **Up-Dosing (Daily Dose Pack) prescriptions**: Establish processes and procedures to verify that the patient is enrolled, the prescriber is certified, and only one dose level is dispensed at a time.

For a **Daily Dose Pack dispensed directly to a patient** by shipping it to them for home use: Establish processes and procedures to verify with the prescriber or healthcare setting and document that the **patient was monitored and previously tolerated the first dose of the new Up-Dosing level**

REMS enrollment confirmation is sent via email to the Authorized Representative. User name and password to access the REMS Verification Portal are sent separately

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REMS Requirements for *Before* Dispensing PALFORZIA

- Initial Dose Escalation
  - Verify the prescriber is certified
  - Verify the patient is enrolled
  - Verify the Initial Dose Escalation is only dispensed to a certified healthcare setting.
- Up-Dosing (Daily Dose Pack) and Maintenance shipped to healthcare setting
  - Verify the patient is enrolled
  - Verify the prescriber is certified
  - Verify only one dose level is dispensed at a time.
    - If the Up-Dosing level is being shipped to a healthcare setting, then the pharmacy must also verify that the healthcare setting is certified in the PALFORZIA REMS Program
- Daily Dose Pack and Maintenance directly to a patient by shipping it to them for home use
  - Verify the patient is enrolled
  - Verify the prescriber is certified
  - Verify only one dose level is dispensed at a time.
  - Verify with the prescriber or healthcare setting and document:
    - The patient was monitored and previously tolerated the first dose of each new Up-Dosing level

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REMS Requirements for Pharmacies

- At all times, the pharmacy will:
  - **Only dispense the Initial Dose Escalation** to a certified healthcare setting
  - **Maintain** patient level dispense data.
  - **Maintain records** that all processes and procedures are in place and are being followed.
  - **Comply with established data requirements, audits and/or surveys** 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
    - PALFORZIA cannot be distributed, transferred, loaned or sold *outside* of your pharmacy
- To maintain certification:
  - Ensure a new Authorized Representative enrolls in the REMS Program by completing the *Pharmacy Enrollment Form* **if the Authorized Representative changes.**

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Change in Authorized Representative

- In the event the Authorized Representative leaves or contact information is updated, the pharmacy must inform the REMS Program Coordinating Center.
- Outreach by the PALFORZIA REMS Program to confirm the Authorized Representative on record is accurate will be performed annually.
  - If the Authorized Representative has changed, the pharmacy is required to submit a new *Pharmacy Enrollment Form* with a current Authorized Representative.
  - If an Authorized Representative is not identified, the pharmacy may be unable to dispense until a representative is identified

Be proactive and communicate any changes in Authorized Representatives to the PALFORZIA REMS Program.

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Monitoring Non-Compliance

- Compliance with REMS requirements is monitored via pharmacy dispense data
  - Examples of Non-Compliance:
    - Prescriptions dispensed to non-enrolled patients
    - Prescriptions dispensed written by a non-certified prescriber
    - Dispensing Initial Dose Escalation (IDE) to a location other than a certified healthcare setting
    - Prescription dispensed to a non-certified healthcare setting
    - Daily Dose Pack dispensed directly to a patient for the first dose of a new Up-Dosing level (ie, not dispensed to a certified healthcare setting)
    - Daily Dose Pack or Maintenance dispensed to a patient's home without verifying the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

***REMINDER**: Confirm patient, prescriber, healthcare setting enrollment and patient dose tolerance and monitoring (as applicable) and obtain authorization code prior to <u>each</u> dispense*

If compliance with the requirements of the PALFORZIA REMS Program are not maintained, the pharmacy may no longer be able to dispense.

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REMS Verification Portal – Live Demo

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REMS Verification Portal – Reminders

- Verification is performed via the REMS Website (www.PALFORZIAREMS.com)
  - Pharmacy Users may log in from the home screen
- Pharmacy staff must verify the prescriber is certified, the patient is enrolled, and the healthcare setting is certified (if shipping to a healthcare setting) prior to each dispense
  - This must be completed for **each** NDC dispensed
- If a healthcare setting, prescriber or patient is ***not*** enrolled, the pharmacy should direct the healthcare setting or prescriber to the REMS website or to contact the REMS Program Coordinating Center to become enrolled
  - Pharmacy staff may also contact the REMS Program directly for support
- Pharmacy staff must record and save the prescriber REMS ID, patient REMS ID, HCS REMS ID or patient dose tolerance confirmation method and authorization code in pharmacy records
  - These fields are required to be returned in the SP dispense file
- If Up-Dosing/Maintenance is being shipped to a HCS, then the HCS must be certified
- Authorization Codes are valid for 7 days after generating
- Authorized Representatives should periodically monitor users that have access to the portal and remove delegates that are no longer required to have access

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Prescriber Status Definitions

REMS Status	Definition
Pending	All required fields on the *Prescriber Enrollment* Form are not present
Certified	**All required fields on the *Prescriber Enrollment Form* are present and the prescriber is REMS certified**
Not Complete	A pending record does not meet all criteria to become certified (due diligence exhausted, declined to complete)
Inactive	Was in a certified status but needs to become inactive (stakeholder request, no longer administering)
De-Certified	Was in a certified status but needs to become de-certified due to non-compliance

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Patient Status Definitions

REMS Status	Definition
Pending	All required fields on the *Patient Enrollment Form* are not present
Enrolled	**All required fields on the *Patient Enrollment Form* are present and the patient is enrolled in the REMS Program**
Not Complete	A pending record does not meet all criteria to become Enrolled (due diligence exhausted, declined to complete)
Inactive	Was in an enrolled status but is now inactive (stakeholder request, no longer taking drug)

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Healthcare Setting Status Definitions

REMS Status	Definition
Pending	All required fields on the *Healthcare Setting Enrollment Form* are not present
Certified	**All required fields on the *Healthcare Setting Enrollment Form* are present and the HCS is REMS certified**
Not Complete	A pending record does not meet all criteria to become certified (due diligence exhausted, declined to complete)
Inactive	Was in a certified status but is now inactive (stakeholder request, no longer administering)
De-Certified	Was in a certified status but is now de-certified due to non-compliance

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Record Maintenance & Dispense File Requirements

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Maintain Proper Records

- Documentation of processes and procedures to support the REMS Program must be maintained and followed
- Pharmacy staff must maintain proper records of the authorization code for each dispense
- The authorization code provided via the REMS Verification Portal is linked to the dispense records to confirm compliance and that unique authorization codes were generated for each dispense

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Pharmacy Dispense Files

- Certified pharmacies are required to provide a file to the REMS Program that includes details of each dispense
  - The intent is to ensure that pharmacies communicate patient dispense data back to the REMS Program on an ongoing basis for compliance monitoring
- Records are processed based on the Data Specification Document that has been agreed upon by Aimmune Therapeutics, Inc. and provided to the pharmacy
  - Records will defer, accept or reject
- The status of a record on a given file is communicated back to the pharmacy via email

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Processing of Dispense Records

Accepted Records:

- Based on defined rules, the record is in the correct format and may be loaded into the REMS database

Deferred Records:

- Based on defined rules, specific data elements that identify potential compliance issues
- Reviewed to confirm record may be accepted or rejected
- Specialty Pharmacy Liaison (SPL) reviews records daily

Rejected Records:

- Based on defined rules, data elements do not meet agreed upon expected response
- SPL or designee reviews records daily
- Sent daily to pharmacy for follow up
- QA File Processing Notification email sent upon receipt of dispense record

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Examples of Deferred and Rejected Records

Deferred Records

- Authorization code is blank
- Patient REMS ID is not in an ‘enrolled’ status
- Duplicate shipment dates
- Duplicate authorization codes
- IDE shipped to patient
- Authorization code generated after ship date
- Patient dose tolerance confirmation in dispense record doesn’t match what was used in shipment verification

Rejected Records

- Field is blank
- Field is not in the proper format as per the Data Specification Document
- Patient REMS ID invalid
- SP Transaction ID invalid

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Record Restatement Process

- Pharmacy data is reviewed for completeness and to ensure the format of each data field is correct
- If a record fails validation for formatting, the record will be rejected, but the REMS Program will continue to process the record and follow up for REMS compliance (as applicable)
- The REMS Specialty Pharmacy Liaison (SPL), or designee, will follow up via email on a weekly basis to ensure all restated records are received
- Records must be restated in less than 3 business days
- If records are not restated in a timely manner, the SPL will follow up via telephone

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Steps to Restate a Record

- Update the record information within the Pharmacy system
- Update the transSeq accordingly indicating the record is a restatement
  - It is essential that the Transaction ID and the transSeq > 0 are provided in the restated record in order to associate the corrected data with the original record
- The Transaction ID of the restatement record must be the same as the Transaction ID of the original record
  - When a corrected record is resubmitted with the original Transaction ID and a transSeq > 0, the system searches the database for a rejected record with the same Transaction ID and compares the information.
- If the restatement record is accepted and passes the validation rules, then the rejected record is updated automatically in the REMS database

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Importance of Accurate Data

- Pharmacy adherence to sending data files and restating records in a timely manner is essential to the program to ensure:
  - Compliance with REMS requirements
  - Data reflected correctly in system
  - REMS metrics are accurately reported to FDA

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Support

www.PALFORZIAREMS.com

Call Toll-Free

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

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PALFORZIA REMS Anaphylaxis Adverse Event Reporting 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:

Anaphylaxis adverse events (including suspected cases managed as anaphylaxis) must be reported to the REMS. If a patient experienced more than one anaphylaxis event, please complete this form for each unique event.

Complete and submit this form to the REMS online at www.PALFORZIAREMS.com or by fax to 1-844-285-2013.

PATIENT INFORMATION *(*indicates required field)*

First Name*:	MI:	Last Name*:
Date of Birth*: (MM/DD/YYYY)	Sex: ☐ Female ☐ Male ☐ Other	Patient REMS ID:
Address 1*:		
Address 2:		
City*:	State*:	ZIP*:

PRESCRIBER INFORMATION *(*indicates required field)*

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

Anaphylaxis Event Characteristics *(* indicates required field)*

Date of Event*:
Date of start of PALFORZIA:
Current PALFORZIA Dose*:
Date of Start of Current PALFORZIA Dose:
How long after the given dose of PALFORZIA did the symptoms start*: _____ hours _____ minutes ☐ Unknown
Description of clinical course*:

Signs and Symptoms*:

(please check all signs and symptoms that were present during the event; for descriptions see Table 1 "Glossary of Terms"):

General: ☐ Sudden Onset ☐ Rapid progression of signs/symptoms

Body System	Major Criteria	Minor Criteria
Dermatological or mucosal	☐ generalized urticaria (hives) ☐ generalized erythema ☐ angioedema, localized or generalized (not hereditary angioedema) ☐ generalized pruritis with skin rash	☐ generalized pruritis without skin rash ☐ generalized prickle sensation ☐ red, itchy eyes
Cardiovascular	☐ measured hypotension ☐ uncompensated shock as indicated by ≥ 3 of the following: ☐ tachycardia ☐ capillary refill time >3 seconds (s) ☐ reduced central pulse volume ☐ decreased level or loss of consciousness	☐ reduced peripheral circulation as indicated by ≥ 2 of the following: ☐ tachycardia ☐ capillary refill time > 3 s, without hypotension ☐ decreased level of consciousness
Respiratory	☐ bilateral wheeze (bronchospasm) ☐ stridor ☐ upper airway swelling (lip, tongue, throat, uvula, or larynx) ☐ respiratory distress with ≥ 2 of the following: ☐ tachypnea ☐ increased use of accessory respiratory muscles (sternocleidosmastoid, intercostals, etc.) ☐ recession ☐ cyanosis ☐ grunting	☐ persistent dry cough ☐ hoarse voice ☐ difficulty breathing without wheeze or stridor ☐ sensation of throat closure ☐ sneezing, rhinorrhea
Gastrointestinal	Not applicable	☐ diarrhea ☐ abdominal pain ☐ nausea ☐ vomiting
Laboratory	Not applicable	☐ mast cell tryptase elevated above upper limit of normal

Epinephrine availability*:

Was epinephrine available to the patient for immediate use at the time of symptom onset? ☐ Yes ☐ No ☐ Unknown

Treatment of Anaphylaxis Event:

Enter all forms of treatment administered including brand name if known (e.g. epinephrine, antihistamines, steroids, etc.)

Treatment	Dosing and Route of Administration	Number of Doses

Outcomes:

Did this anaphylaxis event result in any of the following? *(check all that apply)*

☐ Emergency Department visit ☐ Hospitalization ☐ Intensive Care Unit admission ☐ Death

Reporter Signature ***(* indicates required field)***

I agree to be contacted to provide additional pertinent information regarding reports of anaphylaxis

Printed Name*:

First Name _____ Last Name _____

☐ **Reporter Signature***

Date* _____

Phone Number*:

Email Address:

aimmune THERAPEUTICS

Phone: 1-844-PALFORZ (1-844-725-3679) **www.PALFORZIAREMS.com** **Fax: 1-844-285-2013**

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Version Date 05/24

Appendix (For reference only. Do not transmit.)

Table 1: Glossary of Terms[1,2]

TERM	DESCRIPTION
Abdominal pain	Sensation of discomfort or pain in the abdominal region
Angioedema	Areas of deeper swelling of the skin and/or mucosal tissues in either single or multiple sites which may not be well circumscribed and is usually not itchy. *(Reported symptoms of "swelling of the tongue" or "throat swelling" should not be documented as angioedema unless there is visible skin or mucosal swelling.)*
Capillary refill time greater than 3 seconds	The capillary refill time is the time required for the normal skin color to reappear after a blanching pressure is applied for 5 seconds. It is usually performed by pressing on the nail bed to cause blanching and then counting the time it takes for the blood to return to the tissue, indicated by a pink color returning to the nail. Normally it is less than 3 seconds.
Cyanosis	A dark bluish or purplish discoloration of the skin and/or mucous membranes due to a lack of oxygen in the blood
Diarrhea	Loose or watery stools which may occur more frequently than usual
Dry cough	Rapid expulsion of air from the lungs and not accompanied by expectoration (a non-productive cough)
Erythema	Abnormal redness of the skin without any raised skin lesions
Generalized	Involving more than one body site—that is each limb is counted separately as is the abdomen, back, head and neck.
Grunting	A sudden and short noise with each breath when breathing out
Hoarse voice	An unnaturally harsh cry in an infant or vocalization in a child or adult
Hypotension (measured)	An abnormally low blood pressure documented by appropriate measurement Infants and children—Age specific systolic blood pressure (BP) of less than the 3rd to 5th percentile or greater than a 30% decrease from that person's baseline Adults—Systolic BP of less than 90 mm Hg or greater than 30% decrease from that person's baseline
Localized	Involving one body site only
Loss of consciousness	Total suspension of conscious relationship with the outside world as demonstrated by an inability to perceive and respond to verbal, visual, or painful stimulus
Nausea	An unpleasant sensation vaguely referred to the upper abdominal region (upper region of the abdomen) and the abdomen, with a tendency to vomit
Pruritis or prickle sensation	An unpleasant skin sensation that provokes the desire to rub and/or scratch to obtain relief
Rapid progression	A conventional clinical term without a specific timeframe; as determined by the clinician
Recession (in-drawing or retractions)	Inward movement of the muscles between the ribs (inter-costal), in the lower part of the neck (supra-clavicular or tracheal tug) or below the chest (sub-costal). The movements are usually a sign of difficulty with breathing
Red and itchy eyes	Redness of the whites of the eyes (sclera) with sensation that provokes the desire to rub and/or scratch to obtain relief.
Reduced central pulse volume	Absent or decreased pulse in one of the following vessels—carotid, brachial or femoral arteries
Rhinorrhea	Discharge of thin nasal mucus
Sensation of throat closure	Feeling or perception of throat closing with a sensation of difficulty breathing
Sneezing	An involuntary (reflex), sudden, violent, and audible expulsion of air through the mouth and nose
Stridor	A harsh and continuous sound made on breathing in
Sudden onset	An event that occurred unexpectedly and without warning leading to a marked change in a subject's previously stable condition
Tachycardia	A heart rate that is abnormally high for age and circumstance Infants and children—A heart rate that is above the upper limit expected for age—see Table 2 Adults and adolescents—The term is usually applied to a heart rate above 100 beats per minute

TERM	DESCRIPTION
Tachypnea	Abnormally rapid breathing which is abnormally high for age and circumstance Infants and children—A respiratory rate that is above the upper limit expected for age—see Table 2 Adults—a respiratory rate in excess of 25 breaths per minute
Urticaria (hives)	Localized redness of superficial layers of skin that is itchy, raised, sharply demarcated and transient (that is skin changes at any location are usually present for less than 12 hours)
Vomiting	The reflex act of ejecting the contents of the stomach through the mouth
Wheezing	A whistling, squeaking, musical, or puffing sound made on breathing out

Table 2. Upper limit of heart and respiratory rate in order to define tachycardia and tachypnea[2]

Age in years	Heart rate upper limit in beats per minute	Respiratory rate upper limit in breaths per minute
<1 year	160	60
1-2 years	150	40
2-5 years	140	35
5-12 years	120	30
>12 years	100	16

References

1. Rüggeberg JU, Gold MS, Bayas JM, Blum MD, Bonhoeffer J, Friedlander S, de Souza Brito G, Heininger U, Imoukhuede B, Khamesipour A, Erlewyn-Lajeunesse M, Martin S, Mäkelä M, Nell P, Pool V, Simpson N; Brighton Collaboration Anaphylaxis Working Group. Anaphylaxis: case definition and guidelines for data collection, analysis, and presentation of immunization safety data. Vaccine. 2007 Aug 1;25(31):5675-84. doi: 10.1016/j.vaccine.2007.02.064. Epub 2007 Mar 12. PMID: 17448577.

2. Gold MS, Gidudu J, Erlewyn-Lajeunesse M, Law B; Brighton Collaboration Working Group on Anaphylaxis. Can the Brighton Collaboration case definitions be used to improve the quality of Adverse Event Following Immunization (AEFI) reporting? Anaphylaxis as a case study. Vaccine. 2010 Jun 17;28(28):4487-98. doi: 10.1016/j.vaccine.2010.04.041. Epub 2010 Apr 29. PMID: 20434547.

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:

1. 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.
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 new 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 1 through 17 years. Up-Dosing and Maintenance may be continued in patients 1 year of age and older.

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 new 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 either the Office Dose Kit or the Daily Dose Pack
4. Verify that the patient has injectable epinephrine

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

1. Assess the patient for anaphylaxis

During teatment, before dispensing a Daily Dose Pack directly to the patient for home use, the healthcare setting will:

1. Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

At all times, the healthcare setting will:

1. Report anaphylaxis including suspected cases managed as anaphylaxis to the PALFORZIA REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
   - Online
   - By fax at 1-844-285-2013
2. Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient

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

-- Please Select --

*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 NEW 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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

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

- Assess the patient for anaphylaxis for at least 60 minutes

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY TO THE PATIENT FOR HOME USE:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- 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
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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 ☐ Hosptial Ambulatory Clinic ☐ Other

*Address 1
123 Main Street

Address 2

*City
Philadelphia

*State
PA

*ZIP
99999

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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- 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 NEW 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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

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

- Assess the patient for anaphylaxis for at least 60 minutes

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY TO THE PATIENT FOR HOME USE:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- 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
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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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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

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*Healthcare Setting Name
ABC Healthcare Setting

*Healthcare Setting Type
☐ Independent Practice ☐ Private Group Practice ☐ Outpatient Clinic ☐ Hosptial 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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- 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 NEW 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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

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

- Assess the patient for anaphylaxis for at least 60 minutes

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY TO THE PATIENT FOR HOME USE:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- 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
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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

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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 ☐ Hosptial 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 ☐ Hosptial Ambulatory Clinic ☐ Other

*Address 1
999 Broadway

Address 2

*City
Philadelphia

*State
PA

*ZIP
99999

× 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

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 NEW 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 either the Office Dose Kit or the Daily Dose Pack
- Verify that the patient has injectable epinephrine

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

- Assess the patient for anaphylaxis for at least 60 minutes

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY TO THE PATIENT FOR HOME USE:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- 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
- Only use patient-specific Initial Dose Escalation and Daily Dose Packs for the intended patient
- 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
- <u>Not</u> distribute, transfer, loan, or sell PALFORZIA

☐ *Authorized Representative Signature

CANCEL | CONTINUE

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.

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 new 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 new Up-Dosing level, the prescriber will:

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

During treatment and before prescribing a Daily Dose Pack to be dispensed from a certified pharmacy to a patient for home use, the prescriber will:

1. Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

During treatment and before dispensing a Daily Dose Pack directly from the healthcare setting to the patient for home use, the prescriber will:

1. Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

At all times, the prescriber will:

1. Report anaphylaxis including suspected cases managed as anaphylaxis to the PALFORZIA REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
   - Online
   - By fax at 1-844-285-2013
2. Report patient treatment discontinuation or transfer of care

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 Phone Number

☐ Office Fax Number - Same as above

Office Fax Number

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:

- 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 new 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 NEW UP-DOSING LEVEL, I WILL:

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

DURING TREATMENT BEFORE PRESCRIBING A DAILY DOSE PACK TO BE DISPENSED FROM A CERTIFIED PHARMACY TO A PATIENT FOR HOME USE, I WILL:

- Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY FROM THE HEALTHCARE SETTING TO THE PATIENT FOR HOME USE, I WILL:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- Report treatment discontinuation or transfer of care to the REMS Program

☐ *Prescriber Signature

CANCEL | CONTINUE

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#)
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 Phone Number

Office Fax Number - Same as above

Office Fax Number

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:

- 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 new 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 NEW UP-DOSING LEVEL, I WILL:

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

DURING TREATMENT BEFORE PRESCRIBING A DAILY DOSE PACK TO BE DISPENSED FROM A CERTIFIED PHARMACY TO A PATIENT FOR HOME USE, I WILL:

- Verify the patient was monitored and previously tolerated the first dose of each new Up-Dosing level

DURING TREATMENT BEFORE DISPENSING A DAILY DOSE PACK DIRECTLY FROM THE HEALTHCARE SETTING TO THE PATIENT FOR HOME USE, I WILL:

- Verify the patient was monitored and previously tolerated the first dose of the new Up-Dosing level

AT ALL TIMES:

- Report anaphylaxis including suspected cases managed as anaphylaxis to the REMS Program using the *Anaphylaxis Adverse Event Reporting Form*
- Report treatment discontinuation or transfer of care to the REMS Program

*Prescriber Signature

CANCEL CONTINUE

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.

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 (DAILY DOSE PACK) PRESCRIPTIONS,** my pharmacy will verify:
   - The patient is enrolled
   - The prescriber is certified
   - Only one dose level is dispensed at a time
3. **PRIOR TO DISPENSING A DAILY DOSE PACK DIRECTLY TO A PATIENT BY SHIPPING IT TO THEM FOR HOME USE,** my pharmacy will verify with the prescriber or healthcare setting and document:
   - The patient was monitored and previously tolerated the first dose of each new Up-Dosing level

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)*

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*

Patient Care Forms

- *PALFORZIA REMS Anaphylaxis Adverse Event Reporting Form*

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 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

*Zip Code:

*Search Radius: -- Please Select --

SEARCH

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

Certified Participant Locator

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

Aimmune Therapeutics, Inc.

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

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

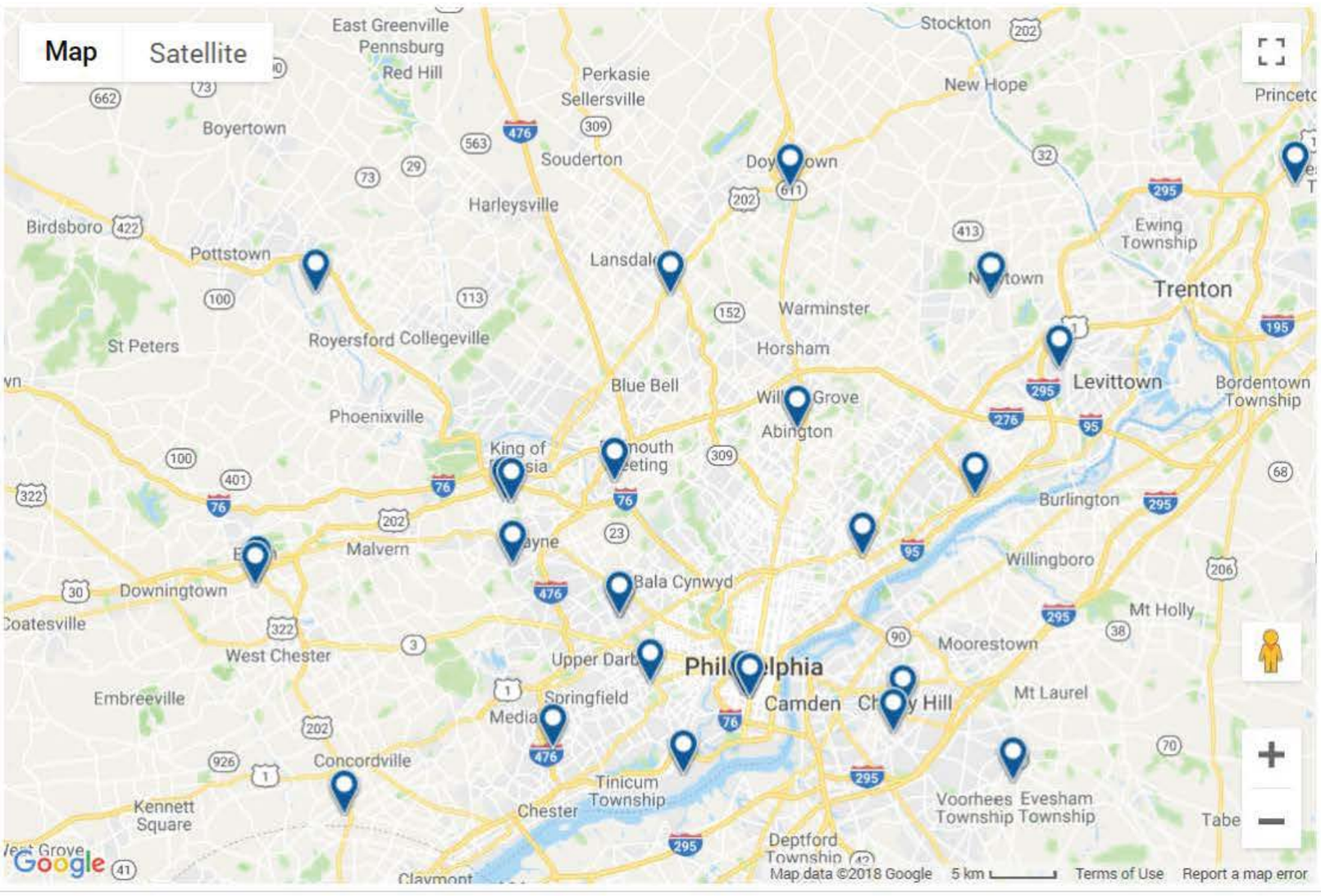
(•) Prescriber/Healthcare Setting ( ) Pharmacy

Certified Prescribers | Certified Healthcare Settings

*Zip Code: 12345

*Search Radius: Within 25 miles

SEARCH



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

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

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

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

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

PRESCRIBER NAME — 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
or call 1-800-FDA-1088 (1-800-332-1088).

Aimmune Therapeutics, Inc.

aimmune THERAPEUTICS

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

Certified Participant Locator

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*Please select a certified participant to locate

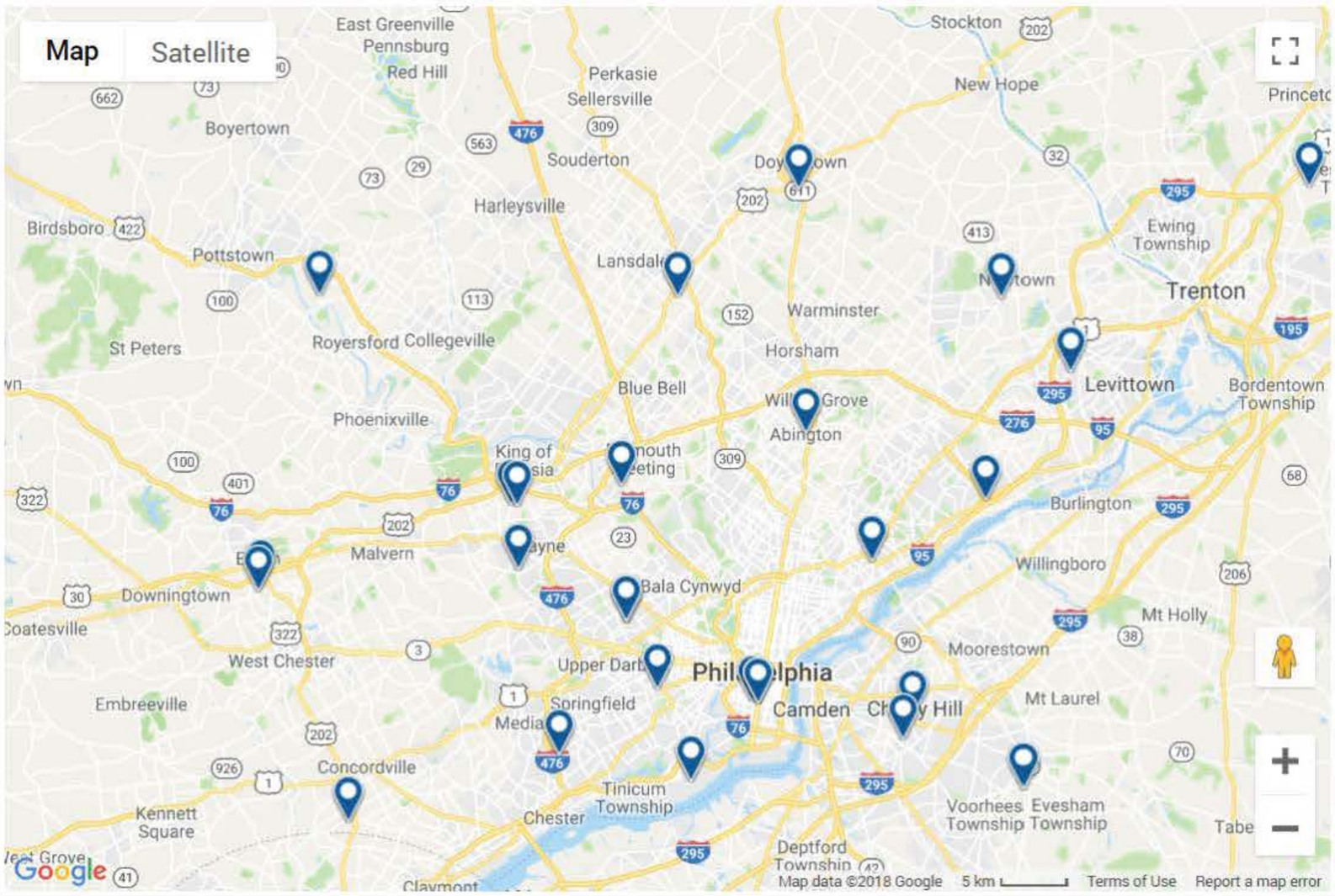
(•) Prescriber/Healthcare Setting ( ) Pharmacy

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 NAMER — 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
eolmjbni
AKIJIWpR
KwKww, PA 19101
555 555-1212
Directions

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).

Aimmune Therapeutics, Inc.

aimmune THERAPEUTICS

Certified Participant Locator

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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

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.

User Name

LOGIN

Forgot Username

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.