GETTING YOUR PRACTICE READY FOR PALFORZIA

A step-by-step checklist to help your practice prepare for implementation

INDICATION

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 for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older.

PALFORZIA is to be used in conjunction with a peanut-avoidant diet.

Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

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

Please see additional Important Safety Information on back cover.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide included in this Resource Kit. PALFORZIA is only available through a REMS program; visit PalforziaREMS.com to learn more.

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

LET'S GET STARTED

Implementation in 4 steps

Follow these step-by-step instructions to get your practice ready to treat with PALFORZIA:

BECOME REMS-CERTIFIED
FIND OUT HOW TO GET CERTIFIED AND ENROLLED IN THE PALFORZIA REMS PROGRAM ☑

ORDER YOUR PALFORZIA OFFICE DOSE KIT (ODK)
GET REGISTERED AND PLACE YOUR ORDER FOR PALFORZIA ☑

IDENTIFY CANDIDATE PATIENTS
DETERMINE IF PALFORZIA COULD BE RIGHT FOR YOUR PATIENTS ☑

PRESCRIBE PALFORZIA
GET CONNECTED WITH A SPECIALTY PHARMACY IN YOUR AREA ☑

1 BECOME REMS-CERTIFIED
ENROLL IN THE REMS PROGRAM TO ADMINISTER PALFORZIA

The first step in prescribing PALFORZIA to your patients is for your practice to become REMS certified.

Visit PalforziaREMS.com to get started and:

WATCH an instructional video to guide you through the certification process

DOWNLOAD the Prescriber Enrollment Form, complete, and submit

ENROLL your eligible patient(s) in the PALFORZIA REMS Program

FIND specialty pharmacies

REMS = Risk Evaluation and Mitigation Strategy.

2 ORDER YOUR PALFORZIA OFFICE DOSE KIT (ODK)
PREPARE FOR IN-OFFICE ADMINISTRATION

Once you and your practice are REMS-certified, you can place your order for your first doses of PALFORZIA for in-office use.

For more information on how to order, log on to **PalforziaOfficeDoseKit.com** or **call 1-844-PALFORZ (1-844-725-3679)**.

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3 IDENTIFY CANDIDATE PATIENTS
DETERMINE WHICH PATIENTS MIGHT BE READY FOR A PROACTIVE APPROACH

When determining if PALFORZIA is right for your patients, you may want to keep the following 3 steps in mind:

IDENTIFY: PALFORZIA may be appropriate for patients 4 through 17 years old with a confirmed diagnosis of peanut allergy and who do not demonstrate contraindications or meet exclusion criteria[1]

EDUCATE: Consider discussing options to start PALFORZIA during your next touchpoint with your patient and caregiver[1]

ENROLL: Certified prescribers must enroll patients in the REMS Program to administer PALFORZIA[1]

Remember, before a patient can begin PALFORZIA treatment, the prescriber and healthcare setting must be certified through the PALFORZIA REMS Program, and your patient must be enrolled.[1] Visit **PalforziaREMS.com** to enroll your patient.

You can also download more materials and a hypothetical patient profile at **PalforziaPro.com/Patient-profile.pdf**

4 PRESCRIBE PALFORZIA
WHEN THEY'RE READY TO BEGIN TREATMENT

After your patient is enrolled in the REMS Program, you can **prescribe PALFORZIA by:**

- Downloading, completing, and submitting the Prescription and Enrollment form
- Finding a specialty pharmacy that will work with you and your patients to dispense PALFORZIA

Contact an Aimmune Allergy Account Manager who can provide a helpful in-service session that covers what you need to know about treatment components and the dosing regimen.

For questions about PALFORZIA access, insurance coverage, or financial assistance, contact the PALFORZIA Pathway™ Support Program at **1-844-PALFORZ (1-844-725-3679)**.

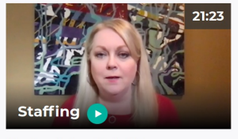
OPTIMIZE YOUR OFFICE

These considerations will help ensure that you and your practice are ready to prescribe PALFORZIA

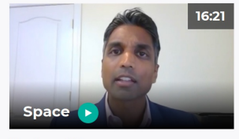
1. **STAFFING**
   Leverage your practice's experience in allergen immunotherapy
2. **SPACE:**
   Designate office space for dose administration and monitoring
3. **SELECTION:**
   Identify patients who may be candidates for treatment and monitoring
4. **SCHEDULING:**
   Determine the best practices for scheduling needs
5. **SUPPORT:**
   Help patients successfully integrate therapy into their daily lives

Be sure to reference the Practice Readiness brochure to help you achieve these 5 key steps.

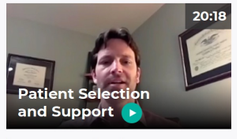
You can also check out videos for each step. Visit **PalforziaPro.com/getstarted** to see our experts talk about the 5S's.



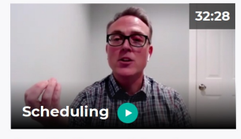
Find out about staffing considerations for your practice.



Review office space considerations for the three phases of treatment.



Learn more about appropriate patients for PALFORZIA and available financial assistance programs.



Consider these points when scheduling patient visits throughout the treatment process.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

All Initial Dose Escalation doses and the first dose of each 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.

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 events reported in subjects treated with PALFORZIA (incidence ≥ 5% and at least 5% greater than 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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Reference: 1. PALFORZIA [package insert]. Brisbane, CA: Aimmune Therapeutics, Inc.

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