PREPARING YOUR PRACTICE FOR IMPLEMENTATION

Clinical and logistical considerations to safely and effectively implement PALFORZIA in your practice

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.

Palforzia™

Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

CONSIDERATIONS AS YOU PREPARE YOUR PRACTICE FOR IMPLEMENTATION

STAFFING

Leverage staff who are experienced in allergen immunotherapy

- [ ] Assist with general inquiries about PALFORZIA
- [ ] Determine in-office process for handling after-hours support
- [ ] Coordinate with support network (eg, HUB, specialty pharmacy, and insurance providers)
- [ ] Identify, assess, and be able to treat and manage peanut allergic reactions, including anaphylaxis
- [ ] Align on PALFORZIA protocols
- [ ] Know how to prescribe and acquire PALFORZIA throughout the treatment pathway
- [ ] Keep intake forms readily available
- [ ] Set up and manage PALFORZIA REMS Program
- [ ] Ensure appropriate medical staff are on site for all PALFORZIA appointments

SPACE

Designate office space for PALFORZIA dosing and post-administration monitoring; consider use of exam rooms and common office areas, like your waiting room

- [ ] Ensure equipment and medications are readily available to treat allergic reactions
- [ ] Provide entertainment for patients and caregivers during observation times (optional)
- [ ] Designate space and staff to provide education to patients and caregivers after dose monitoring
- [ ] Agree upon start-to-finish procedure flow for appointments (eg, PA intake forms)

SUPPORT

Educate patients on what to expect with PALFORZIA treatment, including how dosing may have an impact on their daily routines

- [ ] Educate patient and caregiver on treatment pathway stages (Initial Dose Escalation, Up-Dosing, and Maintenance Dosing)
- [ ] Develop protocol to help patients who experience reactions while dosing at home during practice business hours and after hours
- [ ] Ensure staff understand how to enroll patients in PALFORZIA Pathway and help patients understand the PALFORZIA REMS Program

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

Palforzia Pathway™

SCHEDULING

Determine the best way for your practice to address the scheduling needs for PALFORZIA in-clinic dosing and potential dose adjustments

- [ ] Schedule appointments of sufficient duration for dosing and monitoring
- [ ] Block time for ad hoc appointments for unanticipated dosing adjustments
- [ ] Consider dedicating a day each week for Initial Dose Escalation appointments

SELECTION (PATIENT IDENTIFICATION)

Identify patients who may be PALFORZIA candidates based on their clinical profiles

- [ ] Create a process for identifying appropriate patients for PALFORZIA
- [ ] Establish procedure to assess history of allergic reaction to peanut and other diagnostic tests
- [ ] Discuss additional nonclinical considerations with patients (eg, the importance of attending appointments regularly and taking medication daily)
- [ ] Use shared decision-making with patients to determine whether or not to proceed with treatment

For more information about PALFORZIA, visit PALFORZIAPro.com

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

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

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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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. Reevaluate 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.

Please see accompanying full Prescribing Information, including Boxed WARNING, and Medication Guide.

aimmune THERAPEUTICS

AIMT-PM-USA-0198 04/20

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