TREATMENT PATHWAY

Prepare your practice to support your patients with PALFORZIA.

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.

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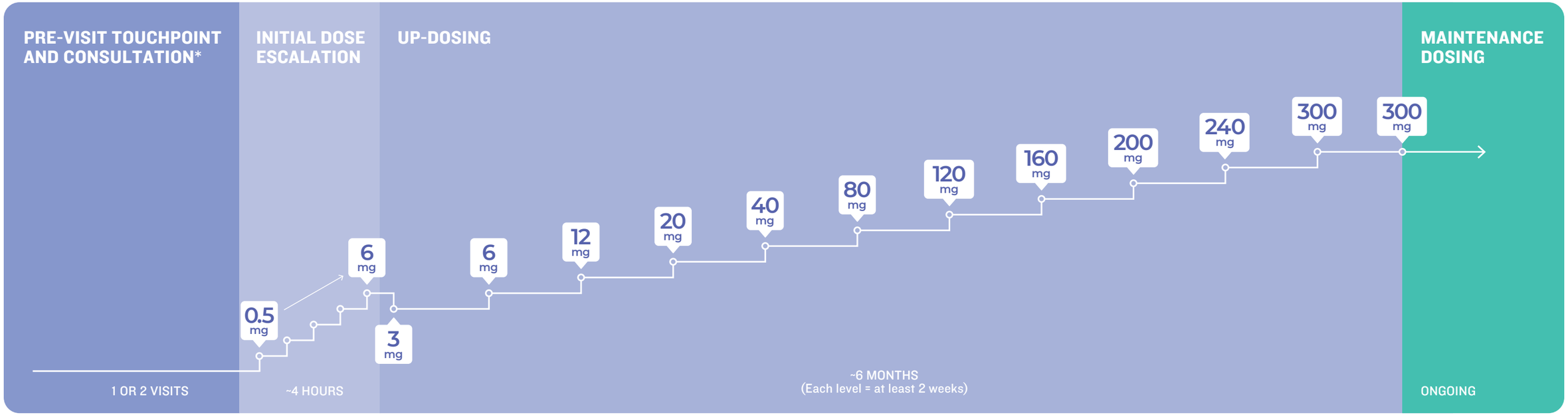
Peanut (*Arachis hypogaea*) Allergen Powder-dnfp

CLEAR STEPS IN THE TREATMENT PATHWAY

After establishing eligibility, patients are exposed to gradually increasing amounts of peanut allergen over a 6-month period, then continue with daily dosing to maintain the effect of PALFORZIA.[1]



*These appointments occur based on the healthcare provider's discretion.

PALFORZIA doses are premeasured in capsules and sachets and packaged for each dose level.

INITIAL DOSE ESCALATION	0.5 mg	1 mg	1.5 mg	3 mg	6 mg						
	1 x 0.5 mg	1 x 1 mg	1 x 0.5 mg 1 x 1 mg	3 x 1 mg	6 x 1 mg						
UP-DOSING	3 mg	6 mg	12 mg	20 mg	40 mg	80 mg	120 mg	160 mg	200 mg	240 mg	300 mg
	3 x 1 mg	6 x 1 mg	2 x 1 mg 1 x 10 mg	1 x 20 mg	2 x 20 mg	4 x 20 mg	1 x 20 mg 1 x 100 mg	3 x 20 mg 1 x 100 mg	2 x 100 mg	2 x 20 mg 2 x 100 mg	
MAINTENANCE DOSING	300 mg										

TIP: Temporary dose modification of PALFORZIA may be required for patients who experience allergic reactions during Up-Dosing or Maintenance, for patients who miss doses, or for practical reasons of patient management.[1]

Please see **Dosing Overview** brochure in the PALFORZIA Resource Kit for more.

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PRE-VISIT TOUCHPOINT AND CONSULTATION*

Once a patient is interested in PALFORZIA, several steps must be completed before treatment begins.

ENROLL in PALFORZIA REMS Program

INITIATE a benefits investigation, prior authorization, and/or medical exception

ORDER relevant lab tests (if necessary)

SCHEDULE Initial Dose Escalation and Up-Dosing visits

PRESCRIBE Initial Dose Escalation Card and ensure Office Dose Kit is available for Day 2 (Up-Dosing)

ORDER 3-mg PALFORZIA Up-Dosing Pack for in-office Up-Dosing

VERIFY the patient has a supply of injectable epinephrine

PROVIDE patient with the Treatment Handbook

*These appointments occur based on the healthcare provider's discretion.

INITIAL DOSE ESCALATION

After identifying appropriate patients, Initial Dose Escalation can begin[1]

REESTABLISH patients' eligibility for PALFORZIA and determine if they can start treatment

ADVISE patients to bring refrigerated or room-temperature, semisolid food to which they are not allergic. Examples: applesauce, yogurt, pudding

ADMINISTER all 5 dose escalations (no dose level should be omitted)

SEPARATE each dose by an observation period of 20 to 30 minutes

OBSERVE patients after the last dose for at least 60 minutes

(Optional) ENCOURAGE patients to bring books, tablets, or other devices for entertainment purposes during this visit

TYPICALLY LASTS AT LEAST

~4 hours

CONSISTS OF

5

dose escalations administered 20-30 mintues apart

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UP-DOSING

A stepwise approach to increased dosing over ~6 months[1]

REPEAT Initial Dose Escalation if patient is not able to initiate Up-Dosing phase within 4 days

(For patients who tolerate at least the 3-mg dose of Initial Dose Escalation) ADMINISTER first 3-mg dose of Up-Dosing in office the day after Initial Dose Escalation.

OBSERVE patients after dose administration for at least 60 minutes

PRESCRIBE 3-mg PALFORZIA Up-Dosing Pack for 2-weeks*

SHIP to patient's home or directly to your office

SCHEDULE next Up-Dosing visit 2 weeks out

REMIND patients that daily dosing between office visits is required

EDUCATE patients on how to recognize the signs and symptoms of anaphylaxis and train them on how to administer injectable epinephrine

PROVIDE doses from the Office Dose Kit (ODK) to patients who receive PALFORZIA shipments at home to ensure they have daily dosing until their shipments arrive

REPEAT this process for the remaining 10 Up-Dosing levels. The first dose of each level must be administered in office

STARTS THE DAY AFTER INITIAL DOSE ESCALATION

THERE ARE

11

Up-Dosing levels

DAILY HOME DOSING

300 mg

Dose adjustments, including temporarily reducing or withholding PALFORZIA doses, may be made at the physician's discretion depending on the patient's ability to tolerate doses and may extend the time for each dose level.

Please see **Dosing Overview** brochure in the PALFORZIA Resource Kit for more.

*If a patient ever needs more than 2 weeks of dosing for any dose level, order multiple Up-Dosing packs for that level.

MAINTENANCE DOSING

Promoting patients from Up-Dosing to Maintenance Dosing[1]

CONFIRM successful completion of the last level of Up-Dosing (300 mg)

DISCUSS the importance of continuing with PALFORZIA Maintenance Dosing to avoid loss of treatment effect

PRESCRIBE PALFORZIA 30-Day Maintenance Dose Pack to be shipped to home

SCHEDULE next office visit at your discretion

Important Reminders:

- DO NOT omit any Up-Dosing level or progress through Up-Dosing more rapidly than every 2 weeks
- The effect of PALFORZIA is only maintained with continued PALFORZIA treatment
- Patient support materials are available from your Aimmune Practice Account Manager
- During Maintenance, contact patient at regular intervals to assess for adverse reactions to PALFORZIA

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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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