

CODING AND BILLING OVERVIEW

Procedures and service codes commonly used for the diagnosis and evaluation of peanut allergy and the administration of PALFORZIA

DOCUMENT UPDATE:

This document includes new coding updates, effective January 1, 2021.

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 last page.

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CODING AND BILLING ALONG THE TREATMENT PATHWAY

PREPARATION	Establish patients' eligibility and prepare them for treatment during the Pre-Visit Touchpoint and Consultation
1 INITIAL DOSE ESCALATION	The Initial Dose Escalation is administered on a single day under the supervision of a healthcare professional. Patients are given 5 subsequently increasing doses of PALFORZIA with 20-30 minutes of observation between each dose and at least 60 minutes of observation after the last dose
2 UP-DOSING	Patients take the first dose of each new dose level in office every 2 weeks, followed by at least 60 minutes of observation, with daily home dosing in between visits
3 MAINTENANCE DOSING	Patients continue daily home dosing at 300 mg, with periodic office visits at the physician's discretion

Disclaimer

Aimmune Therapeutics has developed this overview to provide general coding information related to PALFORZIA. The information provided in this guide contains general reimbursement information only and is not legal advice nor is it advice about how to code, complete, or submit any particular claim for payment. Information provided is not intended to increase or maximize reimbursement by any payer. The information provided represents Aimmune Therapeutics' understanding of current coding and reimbursement policies. Aimmune Therapeutics disclaims all responsibility related to provider billing. It is the provider's responsibility to determine appropriate codes, charges, and modifiers, and submit claims for the services consistent with the payer requirements. Third-party payer policies and coding requirements vary and are updated and changed over time. Providers should check and verify current policies and requirements with the payer for any particular patient.

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ICD-10-CM DIAGNOSIS CODING

International Classification of Diseases, 10th Edition, Clinical Modification (ICD-10-CM) codes are used to identify the patient's condition and reason the patient is receiving treatment.

Potential ICD-10-CM Diagnosis Codes for Allergy and Reactions due to Peanuts¹

Z91.010	Allergy to peanuts
T78.01XA	Anaphylactic reaction due to peanuts, initial encounter
T78.01XD	Anaphylactic reaction due to peanuts, subsequent encounter
T78.01XS	Anaphylactic reaction due to peanuts, sequela

Other Potential ICD-10-CM Diagnosis Codes Commonly Billed by Healthcare Professionals¹

T78.2XXA	Anaphylactic shock, unspecified, initial encounter
T78.2XXD	Anaphylactic shock, unspecified, subsequent encounter
T78.2XXS	Anaphylactic shock, unspecified, sequela
T78.40XA	Allergy, unspecified, initial encounter
T78.40XD	Allergy, unspecified, subsequent encounter
T78.40XS	Allergy, unspecified, sequela

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POTENTIAL CODES FOR SERVICES RELATED TO PALFORZIA

The following codes represent potential options for Initial Dose Escalation and Up-Dosing services related to PALFORZIA. Please note that coding requirements may vary by payer and are provided for informational purposes only.

» Indicates change effective January 1, 2021

Office Visit Evaluation and Management CPT® Codes²

» 99213**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision-making. When using time for code selection, 20-29 minutes of time is spent on the date of the encounter.
» 99214**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision-making. When using time for code selection, 30-39 minutes of time is spent on the date of the encounter.
» 99215**	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision-making. When using time for code selection, 40-54 minutes of time is spent on the date of the encounter.

Ingestion Challenge Test/Rapid Desensitization Procedure CPT Codes²

95076*	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing
95079*	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)
95180	Rapid desensitization procedure, each hour (e.g., insulin, penicillin, equine serum)

E/M = Evaluation and Management
CPT = Current Procedural Terminology

*Recommended for billing for initial visit by the American Academy of Allergy, Asthma & Immunology (AAAAI) and American College of Allergy, Asthma and Immunology (ACAAI).

**Recommended for billing for Up-Dosing services by the AAAAI and ACAAI. These specialty societies indicate that Up-Dosing services are most appropriately coded using an E/M code plus prolonged service code(s) if needed. Please note: both specialty societies also disclaim that Allergy practices should follow health plan and payer policies and guidelines where available even though they may differ from the guidance provided.

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Unlisted Allergy/Clinical Immunology CPT Codes²

95199

Unlisted allergy/clinical immunologic service or procedure

Prolonged Service, Requiring Direct Patient Contact²

» 99415**

Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service)

» 99416**

Prolonged clinical staff service (the service beyond the highest time in the range of total time of the service) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service)

Prolonged Service, With or Without Direct Patient Contact²

» 99417**

Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service, each 15 minutes of total time (List separately in addition to codes 99205, 99215 for office or other outpatient Evaluation and Management service)

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**Recommended for billing for Up-Dosing services by the AAAAI and ACAAI. These specialty societies indicate that Up-Dosing services are most appropriately coded using an E/M code plus prolonged service code(s) if needed. Please note: both specialty societies also disclaim that Allergy practices should follow health plan and payer policies and guidelines where available even though they may differ from the guidance provided.

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TELEHEALTH VISITS

Please note that telehealth appointments cannot replace office visits for Initial Dose Escalation, Up-Dosing, or Maintenance when PALFORZIA is administered and patients are monitored in clinic as described in the REMS (Risk Evaluation and Mitigation Strategy) Program requirements. Please see the full prescribing information or go to www.PALFORZIAREMS.com for more information about REMS requirements. Telehealth visits may be considered for REMS patient enrollment consultations to provide additional information about PALFORZIA or check in discussions as needed between office appointments.

According to the American Medical Association (AMA), **Telehealth** is “a digital health solution that connects the patient and clinician through real-time audio and video technology. It can be used as an alternative to traditional in-person care delivery and, in certain circumstances, can be used to deliver care such as the diagnosis, consultation, treatment, education, care management, and self-management of patients.”³

Telemedicine refers to the tools and platforms that allow clinicians to connect with one another as well as with patients. Telemedicine between patients and clinicians may include synchronous, meaning real-time, audio-video communication, real-time audio and telephone communications as described by the AMA.³

Disclaimer

Coding information for telehealth services is rapidly changing and may vary by payer and are provided for informational purposes only. Please refer to the patient’s insurer for the most up-to-date information and guidance on coding.

Evaluation and Management Visits^{2,4}

99202-99205	Office or other outpatient visit for the evaluation and management of a new patient.
99211-99215	Office or other outpatient visit for the evaluation and management of an established patient.

A list of available codes for telehealth services can be found here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.com>

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ONLINE DIGITAL VISITS

According to the AMA, online digital visits and/or brief check-in services are furnished using communication technology that is employed to evaluate whether or not an office visit is warranted (via patient portal, smartphone).³

Online Digital Visit CPT Codes^{2,4}

99421	Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
99422	11-20 minutes
99423	21 or more minutes
98970	Qualified nonphysician healthcare professional online digital assessment and management, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes
98971	11-20 minutes
98972	21 or more minutes

Online Digital Visit HCPCS Codes^{3,4}

G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment
G2012	Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified healthcare professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
» G2250	Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.
» G2251	Brief communication technology-based service (e.g., virtual check-in), by a qualified healthcare professional who cannot report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion.

E/M = Evaluation and Management

CPT = Current Procedural Terminology

HCPCS = Healthcare Common Procedure Coding System

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TELEPHONE EVALUATION AND MANAGEMENT SERVICE

Evaluation and management visits via audio-only telephone communications⁴

Telephone Evaluation and Management CPT Codes^{2,4}

99441	Telephone evaluation and management service provided by a physician or other qualified healthcare professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion
99442	11-20 minutes
99443	21-30 minutes

E/M = Evaluation and Management
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Place Of Service (POS) Coding⁵

Check with your payer to determine the appropriate Place of Service (POS) code for your telehealth visits. The AMA is aware that some commercial payers are requiring the use of POS 02—Telehealth codes (the location where health services and health-related services are provided or received, through a telecommunication system). Other payers may provide guidance regarding the use of POS code 11.

Modifiers⁵

Some payers may require the use of certain modifiers when billing, for example, Modifier 95 Synchronous telemedicine service rendered via a real-time interactive audio and video telecommunications system. Please check with your patient's insurer to understand their specific policies and guidelines.

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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 \geq 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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References: **1.** The Web's Free 2019 ICD-10-CM/PCS Medical Coding Reference: <https://www.icd10data.com>. Accessed September 9, 2019. **2.** AMA CPT Professional 2021. American Medical Association. **3.** HCPCS Level II Expert 2021. AAPC. **4.** American Medical Association: <https://www.ama-assn.org/system/files/2020-04/ama-telehealth-playbook.pdf>. Accessed November 10, 2020. **5.** American Academy of Pediatrics. Coding for COVID-19 and Non-Direct Care: <https://www.aap.org/en-us/professional-resources/practicetransformation/getting-paid/Coding-at-the-AAP/Pages/default.aspx>. Accessed November 11, 2020.



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