Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Peanut allergy is one of the most common food allergies, affecting over 1 million children in the United States. Peanut allergy typically presents in childhood, and only around 20% of affected individuals will develop tolerance. Allergic reactions to peanuts can be unpredictable and severe, potentially resulting in life-threatening anaphylaxis. Historically, management has focused on strict avoidance of peanut protein and acute treatment of allergic reactions with antihistamines and epinephrine.

Palforzia is an oral immunotherapy agent indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Through gradual dose escalation, Palforzia can help desensitize patients and raise their threshold for allergic reactivity to peanut protein. While not a cure, Palforzia can reduce the incidence and severity of allergic reactions due to unintentional peanut exposure when used in conjunction with peanut avoidance.

NOTE: This policy is specific to Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp], an FDA-approved oral immunotherapy product for peanut allergy. Other forms of allergen immunotherapy are addressed in separate policies:

- Subcutaneous immunotherapy (SCIT) for respiratory and venom allergies - refer to Oscar Clinical Guideline: Allergy (Allergen) Immunotherapy (CG059)
- Sublingual allergen immunotherapy (SLIT) for allergic rhinitis and conjunctivitis - refer to Oscar Clinical Guideline: Allergen Sublingual Immunotherapy (SLIT) (PG093)

  Please consult the relevant policy for specific coverage criteria. The Plan reserves the right to modify these policies and/or create additional policies as treatment options evolve. Providers should review all applicable policies and the member's benefit plan to determine coverage.

Definitions

"**Anaphylaxis**" is a potentially life-threatening systemic hypersensitivity reaction, often involving multiple organ systems such as the skin, gastrointestinal tract, respiratory tract and cardiovascular system.

"**Desensitization**" refers to a temporary increase in the threshold dose of an allergen required to cause allergic symptoms, dependent on regular, ongoing exposure.

"**Oral immunotherapy (OIT)**" is the administration of gradually increasing doses of an allergen to induce a state of desensitization and/or tolerance.

"**Peanut allergy**" refers to an immunoglobulin E (IgE)-mediated hypersensitivity reaction to peanut proteins leading to reproducible allergic symptoms upon exposure.

"**Tolerance**" is the long-term, permanent resolution of allergic responsiveness to a specific allergen, allowing the allergen to be consumed without symptoms even after a period of avoidance.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]** medically necessary when **ALL** of the following criteria are met:

1. Therapy will be initiated and monitored by a physician experienced in the diagnosis and treatment of food allergy (e.g., allergist or immunologist); ***AND***
2. The member is between 1 year of age and 17 years of age; ***AND***

[15] *Continued use into adulthood (18 years and older) may be considered for those who initiated treatment earlier.*

3. The member has a documented diagnosis of of peanut allergy confirmed by **BOTH** of the following:
    a. Physician-documented history of allergic reaction to peanuts (or peanut-containing foods); ***and***
    b. At least **ONE** of the following:
        i. Positive skin prick test to peanut (i.e., mean wheal diameter ≥3 mm larger than negative control)***; or***
        ii. Peanut-specific serum IgE level of >0.35 kU_A/L; ***AND***
4. Palforzia will be used in conjunction with a peanut-avoidant diet; ***AND***
5. The member does **NOT** have **ANY** of the following:
    a. Uncontrolled asthma, defined as frequent asthma exacerbations or persistent symptoms despite treatment; ***and/or***
    b. History of eosinophilic esophagitis or other eosinophilic gastrointestinal disease; ***AND***
6. The member has access to epinephrine (via auto-injector or nasal spray) and has been prescribed and instructed on its use; ***AND***
7. Dose escalation and the first dose of each up-dosing level will be administered under supervision in a healthcare setting capable of treating systemic allergic reactions, including anaphylaxis.

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12-months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating **ALL** of the following criteria:

1. Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] continues to be medically necessary and member is tolerating and adherent to therapy; ***AND***
    a. *For members who have turned 18 while on treatment, the prescriber confirms that continuation of Palforzia is appropriate based on the member's clinical response and risk-benefit assessment.*
2. Prescriber documents clinical benefits of Palforzia therapy, such as:

a. Increased threshold for reactivity to peanut protein as demonstrated by oral food challenge***; or***
b. Reduced frequency and/or severity of allergic reactions to accidental peanut exposure***; or***
c. Improved quality of life scores related to food allergy; ***AND***

3. The member continues to maintain a peanut-avoidant diet and has access to emergency epinephrine (via auto-injector or nasal spray).

Experimental or Investigational / Not Medically Necessary

Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Initiation of Palforzia in members without access to and ability to use epinephrine (i.e., epinephrine auto-injector or epinephrine nasal spray).
- Initiation or continuation of Palforzia in members without a formal diagnosis of peanut allergy confirmed by clinical history and diagnostic testing.
- Initiation or up-dosing of Palforzia therapy in any setting other than a healthcare facility equipped to treat anaphylaxis.
- Use of Palforzia for the treatment of other food allergies or other forms of immunotherapy, as the safety and efficacy for these uses have not been established.
- Use of Palforzia in members under 1 year of age, as the safety and efficacy has not been established.
- Use of Palforzia in members with a history of severe or life-threatening anaphylaxis to peanuts, especially with a history of recent severe or life-threatening reactions, as the safety and efficacy in this population has not been established.
- Use of Palforzia in members with uncontrolled asthma, as these patients were excluded from clinical trials.
- Use of Palforzia to allow for intentional consumption of peanut-containing foods. Palforzia should be used in conjunction with a peanut-avoidant diet.

Applicable Billing Codes (HCPCS/CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
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)
95199	Unlisted allergy/clinical immunologic service or procedure
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 total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.
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 total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.
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 total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.
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)

99417	Prolonged outpatient evaluation and management service(s) time with or without direct patient contact beyond the required time of the primary service when the primary service level has been selected using total time, each 15 minutes of total time (List separately in addition to the code of the outpatient Evaluation and Management service)
C9399	Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] Unclassified drugs or biologicals
J8499	Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] Prescription drug, oral, non chemotherapeutic, nos
ICD-10 codes considered medically necessary if criteria are met:	
Code	*Description*
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
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

References

1. American Academy of Allergy Asthma and Immunology. The current state of oral immunotherapy (OIT) for the treatment of food allergy. Available at: https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/the-current-state-of-oral-immunotherapy.
2. Dunlop JH. Oral immunotherapy for treatment of peanut allergy. J Investig Med. 2020 Aug;68(6):1152-1155. doi: 10.1136/jim-2020-001422. Epub 2020 Jul 14. PMID: 32665367.
3. Du Toit G, Brown KR, Vereda A, Irani AM, Tilles S, Ratnayake A, Jones SM, Vickery BP. Oral Immunotherapy for Peanut Allergy in Children 1 to Less Than 4 Years of Age. NEJM Evid. 2023 Nov;2(11):EVIDoa2300145. doi: 10.1056/EVIDoa2300145. Epub 2023 Oct 23. PMID: 38320526.
4. Hayes, Inc. Hayes Health Technology Assessment. *Oral Immunotherapy with Palforzia (peanut allergen powder-dnfp) for the Management of Peanut Allergy.* Lansdale, PA: Hayes, Inc.; April 30,2020.

5. Nurmatov U, Venderbosch I, Devereux G, Simons FER, Sheikh A. Allergen-specific oral immunotherapy for peanut allergy. Cochrane Database of Systematic Reviews 2012, Issue 9. Art. No.: CD009014. DOI: 10.1002/14651858.CD009014.pub2.
6. Palforzia (peanut [Arachis hypogaea] allergen powder) [prescribing information]. Bridgewater, NJ: Aimmune Therapeutics Inc; July 2024.
7. PALISADE Group of Clinical Investigators; Vickery et al. AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med. 2018 Nov 22;379(21):1991-2001. doi: 10.1056/NEJMoa1812856. Epub 2018 Nov 18. PMID: 30449234.
8. Patrawala M, Shih J, Lee G, Vickery B. Peanut Oral Immunotherapy: a Current Perspective. Curr Allergy Asthma Rep. 2020 Apr 20;20(5):14. doi: 10.1007/s11882-020-00908-6. PMID: 32314071; PMCID: PMC7223701.
9. Pepper et al. Consensus report from the Food Allergy Research & Education (FARE) 2019 Oral Immunotherapy for Food Allergy Summit. J Allergy Clin Immunol. 2020 Aug;146(2):244-249. doi: 10.1016/j.jaci.2020.05.027. Epub 2020 Jun 4. PMID: 32505612.
10. Real-world experience of pediatric patients treated with peanut (Arachis hypogaea) allergen powder-dnfp. Portnoy J, Shroba J, Tilles S, Romdhani H, Donelson SM, Latremouille-Viau D, Bungay R, Chen K, McCann W - Ann Allergy Asthma Immunol - January 1, 2023; 130 (5); 649-656.e4
11. Sampson et al; Practice Parameter Workgroup; Sampson HA, Aceves S, Bock SA, James J, Jones S, Lang D, Nadeau K, Nowak-Wegrzyn A, Oppenheimer J, Perry TT, Randolph C, Sicherer SH, Simon RA, Vickery BP, Wood R. Food allergy: a practice parameter update-2014. J Allergy Clin Immunol. 2014 Nov;134(5):1016-25.e43. doi: 10.1016/j.jaci.2014.05.013. Epub 2014 Aug 28. PMID: 25174862.
12. Shaker M, Greenhawt M. Estimation of Health and Economic Benefits of Commercial Peanut Immunotherapy Products: A Cost-effectiveness Analysis. JAMA Netw Open. 2019 May 3;2(5):e193242. doi: 10.1001/jamanetworkopen.2019.3242. PMID: 31050778; PMCID: PMC6503512.
13. Togias et al. Addendum guidelines for the prevention of peanut allergy in the United States: Report of the National Institute of Allergy and Infectious Diseases-sponsored expert panel. J Allergy Clin Immunol. 2017 Jan;139(1):29-44. doi: 10.1016/j.jaci.2016.10.010. PMID: 28065278; PMCID: PMC5226648.
14. Wood et al. Omalizumab for the Treatment of Multiple Food Allergies. N Engl J Med. 2024 Mar 7;390(10):889-899. doi: 10.1056/NEJMoa2312382. Epub 2024 Feb 25. PMID: 38407394; PMCID: PMC11193494.
15. Worm M, Rak S, de Blay F, et al. Sustained efficacy and safety of a 300IR daily dose of a sublingual solution of birch pollen allergen extract in adults with allergic rhinoconjunctivitis: results of a double-blind, placebo-controlled study. Clin Transl Allergy 2014; 4:7.
16. Zuraw, B. (2021). An overview of angioedema: Clinical features, diagnosis, and management. UpToDate.com. Waltham, MA. Last updated May 27, 2021.

Clinical Guideline Revision / History Information

Original Date: 09/18/2024
Reviewed/Revised: