Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/10/2025

Palforzia™ (peanut (Arachis hypogaea) allergen powder-dnfp)

HCPCS: J3590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age
   b. FDA approved diagnosis
   c. Prescribed by or in consultation with an allergist or immunologist
   d. Documentation of clinical history of allergic reaction following peanut consumption
   e. Documentation of a confirmed diagnosis of peanut allergy confirmed by one of the following:
      i. Peanut-specific skin prick test (SPT)
      ii. Peanut-specific IgE antibodies
   f. Provider attestation that the member will be on a peanut-avoidant diet while on Palforzia therapy
   g. Must have a current prescription for epinephrine and access to an epinephrine autoinjector while using Palforzia
   h. Must not have severe or uncontrolled asthma, severe or life-threatening anaphylaxis in the past 60 days, or eosinophilic esophagitis
   i. Must not be used in combination with Viaskin™ Peanut or other peanut desensitization therapy
   j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that all dose levels of up-dosing have been completed before starting maintenance therapy and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Palforzia is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. It 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 and is not indicated for the emergency treatment of allergic reactions, including anaphylaxis

- The 2010 National Institute of Allergy and Infectious Disease Guidelines for the Diagnosis and Management of Food Allergies in the United States recommend suspecting a food allergy in patients presenting with anaphylaxis upon ingestion of food within minutes to hours of ingesting food; in infants, young children, and selected older children diagnosed with certain disorders, such as moderate to severe atopic dermatitis, eosinophilic esophagitis, enterocolitis, enteropathy, and food protein-induced allergic proctocolitis; and in adults diagnosed with eosinophilic esophagitis. Guidelines state the causative food must be identified through one of the following tests: skin prick tests, intradermal tests, total serum IgE, allergen-specific IgE, atrophy patch test, food elimination diets, or oral food challenges. In clinical trials for Palforzia, the diagnosis of peanut allergy was confirmed through skin prick testing or serum peanut specific IgE levels.

- Palforzia does not provide a cure for peanut allergy but reduces the risk of potentially life-threatening accidental exposure to peanut allergens. Despite the reduced risk of life-threatening reactions, Palforzia does have several serious warnings related to its use, including anaphylaxis. Because of the risk of anaphylaxis, patients should still have a current prescription for epinephrine and access to an epinephrine autoinjector.

- Palforzia has not been studied in patients with severe or uncontrolled asthma, severe or life-threatening anaphylaxis in the past 60 days, or eosinophilic esophagitis. The medication also has warnings surrounding use in patients that develop or have these conditions while on therapy. Due to lack of study information and the warnings surrounding use in these conditions, Palforzia should not be initiated in patients with severe or uncontrolled asthma, severe or life-threatening anaphylaxis in the past 60 days, or eosinophilic esophagitis.

- Palforzia has not been studied and there is no data to support use in combination with other medications used for desensitization of peanut allergy.

References:

1. Palforzia [prescribing information]. Brisbane, CA: Aimmune Therapeutics, Inc.; July 2022.
2. Bunyavanich S, Rifas-Shiman SL, Platts-Mills TA, et al. Peanut allergy prevalence among school-age children in a US cohort not selected for any disease. J Allergy Clin Immunol. 2014; 134 (3): 753 - 5.
3. Gupta RS, Springston EE, Warrier MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. Pediatrics. 2011; 128 (1): e9 - 17.
4. Gupta RS, Warren CM, Smith BM, et al. The public health impact of parent-reported childhood food allergies in the united states. Pediatrics. 2018; 142 (6): e20181235.
5. Bock SA, Munoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. J Allergy Clin Immunol. 2007; 119 (4): 1016 - 18.
6. National Food Death Allergy Registry. Available at: https://www.nationalfoodallergydeathregistry.org/the-registry. Accessed on August 26, 2019.
7. Gupta R, Holdford D, Bilaver L, et al. The economic impact of childhood food allergy in the United States. JAMA Pediatr. 2013; 167 (11): 1026 - 31.
8. Panel NI-SE, Boyce JA, Assa'ad A, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. J Allergy Clin Immunol. 2010; 126 (6 Suppl): S1 - 58.
9. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update-2014. J Allergy Clin Immunol. 2014; 134 (5): 1016 - 25.

10. Sicherer SH, Burks AW, Sampson HA. Clinical features of acute allergic reactions to peanut and tree nuts in children. Pediatrics. 1998; 102 (1): e6.
11. Vickery BP, Vereda A, Casale TB, et al. AR101 oral immunotherapy for peanut allergy. NEJM. 2018; 379: 1991 – 2001.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.8</td><td>Effective Date: 04/10/2025</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.7</td><td>Effective Date: 04/11/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.6</td><td>Effective Date: 04/06/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.5</td><td>Effective Date: 04/14/2022</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.4</td><td>Effective Date: 04/08/2021</td><td>Updated to include standard renewal criteria language to the policy

This policy replaces previously approved criteria that was embedded in a drug review which will be retired</td></tr>
<tr><td>1.3</td><td>Effective Date: 05/01/2020</td><td>UM medical management system update for BCBS

<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date: 04/16/2020</td><td>New full drug review</td></tr>
<tr><td>1.1</td><td>Effective Date: 03/01/2020</td><td>UM medical management system update for BCN

<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.0</td><td>Effecttive Date: 11/07/2019</td><td>Preliminary drug review</td></tr>
</table>

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Palforzia™ (Peanut (Arachis hypogaea) Allergen Powder-dnfp) HCPCS CODE: J3590

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for Palforzia™. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION		PHYSICIAN INFORMATION
Name		**Name**
ID Number		**Specialty**
D.O.B.	☐Male ☐Female	**Address**
Patient weight (in kg)	Date recorded:_____	
Diagnosis		**City /State/Zip**
Drug Name		**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity		**NPI**
Directions		**Contact Person**
Date of Service(s)		**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Initiation or Continuation of treatment? ☐ Initiation ☐ Continuation *Date patient started therapy:* _____
2. Please provide the NPI number for the place of administration: _____
3. **Initiation AND Continuation of Therapy:**
   a. Please check the patient's diagnosis: ☐ Peanut allergy ☐ Other: _____
   b. Does the patient have a clinical history of allergic reaction following peanut consumption?
      ☐ Yes, Please provide the date: _____; What did the patient consume: _____;
      Details regarding the patient allergic reaction: _____
      ☐ no Comment _____
   c. Does the patient have documentation of a confirmed diagnosis of peanut allergy by one of the following?
      ☐ Peanut-specific skin prick test (SPT) Date: _____
      ☐ Peanut-specific IgE antibodies Date: _____
   d. Will the provider attest that the member will be on a peanut-avoidant diet while on Palforzia therapy?
      ☐ Yes ☐ No Comment _____
   e. Does the patient have a current prescription for epinephrine and access to an epinephrine autoinjector while using Palforzia?
      ☐ Yes ☐ No Comment _____
   f. Does the patient have severe or uncontrolled asthma?
      ☐ Yes ☐ No Comment _____
   g. Does the patient have eosinophilic esophagitis?
      ☐ Yes ☐ No Comment _____
   h. Has the patient had severe or life-threatening anaphylaxis in the past 60 days?
      ☐ Yes ☐ No Comment _____
   i. Will the patient be receiving Viaskin Peanut or other peanut desensitization therapy while on Palforzia?
      ☐ Yes ☐ No Comment: _____
4. **Continuation Request** (please answer questions above as well): Palforzia start date: _____
   a. Have all dose levels of up-dosing been completed before starting maintenance therapy?
      ☐ Yes ☐ No Comment: _____
   b. How has the patient improved while on Palforzia?
      ☐ Palforzia is providing clinical benefit ☐ Other: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ Concurrent Medical Problems ☐ Prior Therapies
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

2/26/2020; 4/16/2020; 4/8/2021