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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.

Effective Date: 10/07/2021

Viaskin Peanut® (peanut immunotherapy transdermal patch)

FDA approval: Anticipated 3rd Quarter 2020

HCPCS: J3490

Benefit: Medical and Pharmacy

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 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 Viaskin Peanut therapy
 - g. Must have a current prescription for epinephrine and access to an epinephrine autoinjector while using Viaskin Peanut
 - h. Must not have uncontrolled asthma or a history of anaphylaxis
 - i. Must not be used in combination with Palforzia or and other peanut desensitization therapy
 - j. Trial and failure, contraindication, or intolerance to the preferred products as specified in the BCBSM/BCN utilization management medical drug list and/or the BCBSM/BCN prior authorization and step therapy documents

- B. Quantity Limitations, Authorization Period and Renewal Criteria
 - a. Quantity Limit: Align with FDA recommended dosing
 - b. Initial Authorization Period: 1 year at a time
 - c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

***Note: Coverage 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.

Therapeutic considerations:

A. FDA approved indication / Diagnosis

**Please refer to most recent prescribing information.*

B. Background Information

- a. Peanut is a common childhood allergen in the United States
- b. According to recent estimates approximately 1.4 - 4.5% of children in the US suffer from peanut allergy
- c. The number of estimated children effected has risen steadily over the past 20 years
- d. Food allergy reactions can range from mild cutaneous symptoms, to gastrointestinal symptoms such as abdominal pain, nausea, vomiting, and diarrhea, on to anaphylaxis
- e. The allergy usually begins early in life and only a minority of patients outgrow their food allergy
- f. Up to 55% of patients with peanut allergy suffer from additional food allergies
- g. Peanut allergy is the leading cause of death from anaphylaxis due to food, though the rate is low at fewer than four deaths per year over the past 10 years in the US
- h. The economic cost of food allergies is estimated at \$24.8 billion per year, of which only \$4.3 billion was direct medical costs
- i. Treatment guidelines recommend suspecting a food allergy in the following situations:
 - i. Patients presenting with anaphylaxis upon ingestion of food within minutes to hours of ingesting food
 - ii. 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
 - iii. In adults diagnosed with eosinophilic esophagitis
- j. Medical history and physical examination should aid in the diagnosis
- k. The causative food must be identified through one of the following tests:
 - i. Skin prick tests
 - ii. Intradermal tests
 - iii. Total serum IgE
 - iv. Allergen-specific IgE
 - v. Atrophy patch test
 - vi. Food elimination diets
 - vii. Oral food challenges
- l. The primary approach to managing food allergies is to avoid the trigger
- m. Epinephrine is the mainstay of treatment for anaphylaxis due to food allergy
- n. Adjunctive therapy to epinephrine includes β -agonists, H₁-antihistamines, supplemental oxygen therapy, and IV fluids
- o. The current American Academy of Allergy, Asthma, and Immunology treatment guidelines do not recommend the use of allergen-specific immunotherapy to treat food allergies and concluded that the safety and efficacy of oral and sublingual immunotherapy for food hypersensitivity is currently investigational

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

**Please refer to most recent prescribing information.*

E. Dosing and administration

**Please refer to most recent prescribing information.*

F. How supplied

**Please refer to most recent prescribing information.*

References:

1. 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): 753-755.
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4. Bock SA, Munoz-Furlong A, Sampson HA. Further fatalities caused by anaphylactic reactions to food, 2001-2006. *J Allergy Clin Immunol.* 2007; 119 (4): 1016-1018.
5. National Food Death Allergy Registry. Available at: <https://www.nationalfoodallergydeathregistry.org/the-registry>. Accessed on: August 26, 2019.
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7. 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.
8. Sampson HA, Aceves S, Bock SA, et al. Food allergy: a practice parameter update-2014. *J Allergy Clin Immunol.* 2014; 134 (5): 1016-1025.
9. Sicherer SH, Burks AW, Sampson HA. Clinical features of acute allergic reactions to peanut and tree nuts in children. *Pediatrics.* 1998; 102 (1): e6.
10. Cox L, Nelson H, Lockey R, et al. Allergen immunotherapy: a practice parameter third update. *J Allergy Clin Immunol.* 2011; 127 (1): S1-S55.
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12. Togias A, Cooper SF, Acebal ML, 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. *World Allergy J.* 2017; 10 (1).
13. Fleischer DM, Greenhawt M, Sussman G, et al. Effect of epicutaneous immunotherapy vs placebo on reaction to peanut protein ingestion among children with peanut allergy: the PEPITES randomized clinical trial. *JAMA.* 2019; 321 (10): 946 – 55.

Policy/UM Medical Management System Update History												
#	Date	Change Description										
1.2	Effective Date: 10/07/2021	Annual review – no changes to the criteria at this time										
1.1	Effective Date: 10/08/2020	Updated preliminary criteria to mirror what is in place for Palforzia including the addition of documentation of reaction to peanuts, updates to the type of testing required to confirm peanut allergy, and attestation of peanut-free diet.										
1.0	Effective Date: 11/07/2019	Preliminary Drug Review <table border="1" data-bbox="483 472 1362 682" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>No</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* 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>.