

<b>ISSUE DATE</b> December 14, 2020	<b>EFFECTIVE DATE</b> January 5, 2021	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Palforzia [peanut (Arachis hypogaea) allergen powder] – Pharmacy Services		<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: <https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx>.

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (Department) will require prior authorization of prescriptions for Palforzia [peanut (Arachis hypogaea) allergen powder].
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Palforzia [peanut (Arachis hypogaea) allergen powder] submitted for prior authorization.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Palforzia [peanut (Arachis hypogaea) allergen powder] to the appropriate managed care organization.

*01-20-57	09-20-56	27-20-52	33-20-53
02-20-50	11-20-50	30-20-49	
03-20-50	14-20-51	31-20-57	
08-20-60	24-20-51	32-20-49	

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at  
<https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx>.

**BACKGROUND:**

The Department's Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

**DISCUSSION:**

Palforzia [peanut (*Arachis hypogaea*) allergen powder] was recently approved by the U.S. Food and Drug Administration for the mitigation of allergic reactions that may occur with accidental exposure to peanuts. During the October 21, 2020, meeting, the DUR Board recommended that the Department require prior authorization of Palforzia [peanut (*Arachis hypogaea*) allergen powder] to ensure appropriate patient selection and drug utilization. The DUR Board recommended guidelines to determine medical necessity of prescriptions for Palforzia [peanut (*Arachis hypogaea*) allergen powder] that were subject to public review and comment and subsequently approved for implementation by the Department.

**PROCEDURE:**

The procedures for prescribers to request prior authorization of Palforzia [peanut (*Arachis hypogaea*) allergen powder] are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Palforzia [peanut (*Arachis hypogaea*) allergen powder] when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

**ATTACHMENTS:**

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

**RESOURCES:**

Prior Authorization of Pharmaceutical Services Handbook – SECTION I  
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II  
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**I. Requirements for Prior Authorization of Palforzia (Peanut Allergen Powder-dnfp)**

**A. Prescriptions That Require Prior Authorization**

All prescriptions for Palforzia must be prior authorized.

**B. Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for Palforzia, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a clinical history of allergy to peanuts or peanut-containing foods and at least **one** of the following:
  - a. A positive skin prick test (SPT) to peanut  $\geq$  3 mm compared to control,
  - b. A positive serum immunoglobulin E (IgE) test to peanut  $>$  0.35 KU<sub>A</sub>/L,
  - c. An Ara h 2 sIgE  $>$  0.35 KU<sub>A</sub>/L,
  - d. A positive medically supervised oral food challenge;

**AND**

2. Is age-appropriate according to the U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
4. Is prescribed Palforzia by an appropriate specialist (e.g., allergist/immunologist); **AND**
5. Does not have a history of a contraindication to the prescribed medication; **AND**
6. Has received instruction to use Palforzia in conjunction with a peanut-avoidant diet; **AND**
7. Has documentation of receiving or being prescribed injectable epinephrine; **AND**
8. If a prescription for Palforzia is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

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NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PALFORZIA: The determination of medical necessity of a request for renewal of a prior authorization for Palforzia that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability to Palforzia; **AND**
2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Is prescribed Palforzia by an appropriate specialist (e.g., allergist/immunologist); **AND**
4. Does not have a history of a contraindication to the prescribed medication; **AND**
5. Is using Palforzia in conjunction with a peanut-avoidant diet; **AND**
6. Has documentation of receiving or being prescribed injectable epinephrine; **AND**
7. Is able to adhere with the daily dosing requirements included in the package labeling; **AND**
8. If a prescription for Palforzia is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: <https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx>.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Palforzia. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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D. Dose and Duration of Therapy

Requests for prior authorization of Palforzia will be approved as follows:

1. Initial requests for prior authorization of Palforzia will be approved for up to 6 months.
2. Renewals of requests for prior authorization of Palforzia will be approved for up to 12 months.

E. References

1. Greenhawt, Matthew et al. "Peanut Allergy Diagnosis- a 2020 Practice Parameter Update, Systematic Review, and GRADE Analysis." *The Journal of allergy and clinical immunology*, S0091-6749(20)31137-4. 15 Aug. 2020, doi:10.1016/j.jaci.2020.07.031
2. Lieberman JA. Severity of peanut allergy and the unmet gaps in care: a call to action. *Am J Manag Care*. 2018;24(19 Suppl):S412-S418.
3. NIAID-Sponsored Expert Panel, 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-S58. doi:10.1016/j.jaci.2010.10.007
4. Palforzia Package Insert. Brisbane, CA: Aimmune Therapeutics, Inc.; January 2020.
5. PALISADE Group of Clinical Investigators, Vickery BP, Vereda A, et al. AR101 Oral Immunotherapy for Peanut Allergy. *N Engl J Med*. 2018;379(21):1991-2001. doi:10.1056/NEJMoa1812856
6. 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. *Pediatric Dermatology*. 2017 Jan;34(1):e1-e21. DOI: 10.1111/pde.13093.