Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	April 14, 2020 November 12, 2021

PALFORZIA™ (Peanut (*Arachis hypogaea*) Allergen Powder-dnfp)

LENGTH OF AUTHORIZATION: Initial: 8 months
Continuation of therapy: 1 year

INITIAL REVIEW CRITERIA:

- Patient must be 4 to 17 years of age; **AND**
- Prescriber in consultation with a specialist (Allergy and Immunology specialists); **AND**
- Used in conjunction with peanut allergen avoidance; **AND**
- Patient must have a documented clinical history and confirmed diagnosis of allergy to peanuts or peanut-containing foods; **AND**
- Confirmation of a positive skin prick test (wheal diameter ≥ 3 mm) and/or peanut specific IgE (≥ 0.35 kUA/L); **AND**
- Patient has been prescribed and/or has a refill history of epinephrine auto-injector; **AND**
- Patient/caregiver will adhere to the complex up-dosing schedule that requires frequent visits to the administering healthcare facility.

AND

Patient does ***NOT*** have any of the following:

- Severe asthma (e.g., currently treated with high-dose inhaled corticosteroid/long-acting beta-agonist therapy; has forced expiratory volume in 1 second [FEV1] < 60% of predicted); **OR**
- Persistently uncontrolled mild to moderate asthma (defined as FEV1 < 80% predicted; **OR**
- Three to four of the following symptoms: daytime asthma symptoms > twice/week, and nighttime awakening due to asthma symptoms, asthma reliever medication use > twice/week [excluding reliever taken for exercise], or any activity limitation due to asthma); **OR**
- A history of eosinophilic esophagitis, and/or other eosinophilic gastrointestinal diseases. **OR**
- Experienced severe or life threatening anaphylaxis resulting in hypotensive shock, use of > 2 doses of epinephrine, and/or intubation within the prior 60 days; **OR**
- A history or cardiovascular disease; including uncontrolled or inadequately controlled hypertension; **OR**
- A history of mast cell disorder including urticarial pigmentosa, mastocytosis, and hereditary or idiopathic angioedema.

CONTINUATION OF THERAPY:

- Patient must continue to meet the above initial criteria; **AND**
- Patient must continue to tolerate the prescribed daily doses of Palforzia; **AND**
- Patient has not experienced recurrent asthma exacerbations; **AND**

- Patient has not experienced any treatment-restricting adverse effects (e.g., repeated systemic allergic reaction and/or severe anaphylaxis).

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 0.5 mg, 1 mg, 10 mg, 20 mg, and 100 mg capsules and 300 mg sachets.