SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process may be delayed.**

Drug Requested: Palforzia® [Peanut (Arachis hypogaea) Allergen Powder-dnfp] **(Pharmacy)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Sentara #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Medication	Quantity Limit
Palforzia Initial Dose Escalation Kit	1 kit per 365 days
Palforzia Up-Dosing Kits (Levels 1-11)	1 kit per 365 days
Palforzia 300 mg sachets	1 sachet per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ❑ Member must have diagnosis of peanut allergy
- ❑ Member must be at least 4-17 years of age at initiation of therapy
- ❑ Prescribed by or in consultation with an Allergist or Immunologist

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- ❑ Provider has submitted documentation to confirm diagnosis of peanut allergy via **ONE** of the following:
  - ❑ Member has a diagnosis and clinical history of peanut allergy as documented by **BOTH** of the following **(must submit labs and skin prick test results for documentation)**:
    - ❑ A serum peanut-specific IgE level of ≥ 0.35 kUA/L
    - ❑ A mean wheal diameter that is at least 3 mm larger than the negative control on skin prick test for peanut
  - ❑ In the absence of positive clinician supervised food challenge, peanut allergy is confirmed by the **BOTH** of the following:
    - ❑ Positive skin prick test to peanut ≥ 8 mm compared to control, unless skin testing is contraindicated
    - ❑ Serum IgE to peanut ≥ 14 kUA/L
- ❑ Palforzia will be used in conjunction with a peanut-avoidance diet
- ❑ Member must be prescribed injectable epinephrine **(verified by chart notes or pharmacy paid claims)**
- ❑ Member and/or caregiver has been instructed and trained on the appropriate use of injectable epinephrine
- ❑ Health care provider, health care setting, and member **MUST** be enrolled in the Palforzia REMS program
- ❑ Request for Palforzia may **NOT** be approved if member has **ANY** of the following:
  - Severe or poorly controlled asthma
  - History of eosinophilic esophagitis or other eosinophilic gastrointestinal disease
  - History of severe or life-threatening episodes of anaphylaxis or anaphylactic shock within the past 2 months
  - History of mast cell disorder (including mastocytosis), urticarial pigmentosa, hereditary or idiopathic angioedema or currently has paid claims for Berinert, Cinryze, Haegarda, Firazyr, Takhyzyro or Ruconest
  - Individual is in buildup phase of immunotherapy to another allergen (i.e. has not reached maintenance dosing)

Reauthorization: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Provider please note: a one-time reauthorization is required after initial 12 month approval

- ❑ Member must continue to tolerate the prescribed daily dose of Palforzia®
- ❑ Member is compliant with Palforzia® therapy **(verified by pharmacy paid claims)**
- ❑ Member has **NOT** experienced recurrent asthma exacerbations

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- ❑ Member has **NOT** experienced any treatment-restricting adverse effects (e.g., repeated systemic allergic reaction and/or severe anaphylaxis)

Dosing Tables

Table 1: Dosing Configuration for Initial Dose Escalation (Single Day Dose Escalation); supplied as a single card consisting of 5 blisters containing a total of 13 capsules

Dose Level	Total Dose	Dose Configuration
A	0.5 mg	One 0.5 mg capsule
B	1 mg	One 1 mg capsule
C	1.5 mg	One 0.5 mg capsule; One 1 mg capsule
D	3 mg	Three 1 mg capsules
E	6 mg	Six 1 mg capsules

Table 2: Daily Dosing Configuration for Up-Dosing

Dose Level	Total Daily Dose	Daily Dose Configuration	Dose Duration (weeks)
1	3 mg	Three 1 mg capsules	2
2	6 mg	Six 1 mg capsules	2
3	12mg	Two 1 mg capsules; One 10 mg capsule	2
4	20 mg	One 20 mg capsule	2
5	40 mg	Two 20 mg capsules	2
6	80 mg	Four 20 mg capsules	2
7	120 mg	One 20 mg capsule; One 100 mg capsule	2
8	160 mg	Three 20 mg capsules; One 100 mg capsule	2
9	200 mg	Two 100 mg capsules	2
10	240 mg	Two 20 mg capsules; Two 100 mg capsules	2
11	300 mg	One 300 mg sachet	2

Table 3: Daily Dosing Configuration for Maintenance

Dose Level	Total Daily Dose	Daily Dose Configuration
11	300 mg	One 300 mg sachet

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****