SmartPA Criteria Proposal

Drug/Drug Class:	Palforzia Clinical Edit
First Implementation Date:	February 26, 2021
Proposed Date:	October 17, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Palforzia® [Peanut (Arachis hypogaea) Allergen Powder-dnfp]

Why Issue Selected: Palforzia® [Peanut (Arachis hypogaea) Allergen Powder-dnfp] was FDA approved on January 31, 2020, for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is only approved for use in patients with a confirmed diagnosis of peanut allergy and must be used in conjunction with a peanut-avoidant diet. Food allergies affect roughly 8% of children in the US and are on the rise. Such allergies have risen 50% since 1997 and peanut allergies specifically have increased approximately 2% in children since 1999. Peanut allergies are thought to affect more than 1.6 million children and teens in the United States. Palforzia is an oral immunotherapy which desensitizes patients to peanut protein over time; in clinical studies 67.2% of Palforzia treated patients were able to tolerate a 600mg dose of peanut protein after 6 months of maintenance therapy with no more than mild allergic symptoms. Due to the risk of anaphylaxis, Palforzia is only available through the Palforzia REMS program.

Program-Specific Information:

Date Range FFS 7-1-2022 to 6-30-2023			
Drug	**Claims**	**Spend**	**Average Spend per Claim**
PALFORZIA INITIAL DOSE PACK	2	$93.06	$46.53
PALFORZIA 3 MG (LEVEL 1)	2	$1,135.53	$567.77
PALFORZIA 6 MG (LEVEL 2)	1	$593.11	$593.11
PALFORZIA 12 MG (LEVEL 3)	1	$593.11	$593.11
PALFORZIA 20 MG (LEVEL 4)	1	$593.11	$593.11
PALFORZIA 40 MG (LEVEL 5)	1	$593.11	$593.11
PALFORZIA 80 MG (LEVEL 6)	1	$593.11	$593.11
PALFORZIA 120 MG (LEVEL 7)	2	$1,186.22	$593.11
PALFORZIA 160 MG (LEVEL 8)	2	$1,186.22	$593.11
PALFORZIA 200 MG (LEVEL 9)	1	$593.11	$593.11
PALFORZIA 240 MG (LEVEL 10)	1	$593.11	$593.11
PALFORZIA 300 MG (LEVEL 11)	1	$542.42	$542.42

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Palforzia® [Peanut (Arachis hypogaea) Allergen Powder-dnfp]
- Age range: All appropriate MO HealthNet participants aged 4 years or older

Approval Criteria

Initial Therapy:

- Participant age is ≥ 4 years and < 18 years **AND**
- Documented diagnosis of peanut allergy **AND**
- Prescribed by or in consultation with an allergist **AND**
- Documentation of at least 1 paid claim for self-injectable epinephrine in the past year **AND**
- Provider attests that the participant is informed of the need:
  - To have injectable epinephrine available for immediate use at all times **AND**
  - For monitoring with the Initial Dose Escalation and first dose of each Up-Dosing level **AND**
  - For continued dietary peanut avoidance **AND**
  - To recognize the signs and symptoms of anaphylaxis

Continuation of Therapy:

- Initial approval is for 3 months, renewal of prior authorization may be given for up to 12 months with the following:
  - Demonstration of participant compliance with dosing regimen (30/60 days) **AND**
  - Documentation of at least 1 paid claim for self-injectable epinephrine in the past 2 years
- Participants aged ≥ 18 years may continue current therapy if above criteria are met

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented diagnosis of any of the following:
  - Asthma with evidence of inadequate control
  - Eosinophilic esophagitis or other eosinophilic gastrointestinal disease

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

References

- Palforzia [package insert]. Brisbane, CA: Aimmune Therapeutics; March 2023.
- IPD Analytics. “Aimmune Therapeutics’ Palforzia Approved for Treating Peanut Allergy.” Accessed 4 February 2020.
- IPD Analytics. New Drug Review: Palforzia (peanut allergen powder-dnfp). February 2020.
- Center for Disease Control and Prevention. Food Allergies. https://www.cdc.gov/healthyschools/foodallergies/. Accessed September 11, 2023.
- American Academy of Allergy, Asthma and Immunology. “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.” https://www.aaaai.org/global/search?cx=010195695855076926430%3A3j7wmn664zg&cof=FORID%3A11&q=peanut+allergy. Accessed September 11, 2023.
- NIH U.S. National Library of Medicine: Clinical Trials.gov. “Peanut Allergy Oral Immunotherapy Study of AR101 for Desensitization in Children and Adults (PALISADE). https://clinicaltrials.gov/ct2/show/record/NCT02635776?cond=peanut+allergy&draw=2&rank=3. Accessed May 16, 2022.
- NIH U.S. National Library of Medicine: Clinical Trials.gov. “Real-World AR101 Market-Supporting Experience Study in Peanut-Allergic Children.” https://clinicaltrials.gov/ct2/show/NCT03126227?term=NCT03126227&draw=2&rank=1. Accessed May 16, 2022.