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:

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Claims</th>
<th>Spend</th>
<th>Average Spend per Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>PALFORZIA INITIAL DOSE PACK</td>
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<td>$109.50</td>
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<tr>
<td>PALFORZIA 3 MG (LEVEL 1)</td>
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<td>PALFORZIA 6 MG (LEVEL 2)</td>
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<td>PALFORZIA 12 MG (LEVEL 3)</td>
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<td>PALFORZIA 20 MG (LEVEL 4)</td>
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<td>PALFORZIA 40 MG (LEVEL 5)</td>
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</table>
### Type of Criteria:
- [ ] Increased risk of ADE
- [x] Preferred Drug List
- [x] Appropriate Indications
- [ ] Clinical Edit

### Data Sources:
- [ ] Only Administrative Databases
- [x] 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

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Default Approval Period

3 months

References