Clinical Policy: Peanut Allergen Powder (Palforzia)
Reference Number: CP.PMN.220
Effective Date: 03.01.20
Last Review Date: 02.20
Line of Business: Commercial, TBD HIM*, Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

*For Health Insurance Marketplace members, if request is through the pharmacy benefit, this policy applies only when the referenced drug is on the health plan approved formulary. Request for non-formulary drugs must be reviewed using the policy: HIM.PA.103.

Description
Peanut, Arachis hypogaea, allergen powder (Palforzia™) is an oral immunotherapy.

FDA Approved Indication(s) [Pending]
Palforzia is indicated to reduce the incidence and severity of allergic reactions, including anaphylaxis after accidental exposure to peanut in patients aged 4 through 17 years with a confirmed diagnosis of peanut allergy.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Palforzia is medically necessary when the following criteria are met:

I. Initial Approval Criteria*
   *Criteria will mirror the clinical information from the prescribing information once FDA-approved
   A. Peanut Allergy (must meet all):
      1. Diagnosis of peanut allergy;
      2. Prescribed by or in consultation with an allergist or immunologist;
      3. Age ≥ 4 years and ≤ 17 years;*
      4. Confirmation of positive skin test or peanut-specific serum IgE;
      5. Palforzia is prescribed concurrently with injectable epinephrine;
      6. Medical justification supports necessity for oral immunotherapy in addition to peanut avoidance (e.g., member has had previous history of severe reactions to peanuts, member has a severe peanut allergy that can be triggered by smell);
      7. Dose does not exceed 300 mg per day.*
   Approval duration: 6 months

B. Other diagnoses/indications
   1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is
II. Continued Therapy*
*Criteria will mirror the clinical information from the prescribing information once FDA-approved

A. Peanut Allergy (must meet all):
   1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   2. If the member has required usage of injectable epinephrine that exceeds the health plan quantity limit, medical justification supports continued therapy with Palforzia;
   3. Age ≤ 17 years;*
   4. If request is for a dose increase, new dose does not exceed 300 mg per day.*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

   Approval duration: Duration of request or 12 months (whichever is less); or

   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
REMS: Risk Evaluation Mitigation Strategy

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending
- Palforzia will likely have a Risk Evaluation Mitigation Strategy (REMS) program with the following requirements:
  o Documentation that the patient has a prescription for injectable epinephrine
  o Caregiver and patient attestation that they will carry injectable epinephrine while taking Palforzia
• Initial dose escalation and each up-dosing level must be administered in a certified facility capable of treating systemic allergic reactions

V. Dosage and Administration [Pending]

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>Peanut allergy</td>
<td>• Initial dose escalation: 0.5 to 6 mg PO over 1 day&lt;br&gt;• Up-dosing: 3 mg PO with up-dosing every 2 weeks as tolerated until the maintenance dose is reached&lt;br&gt;• Maintenance dose: 300 mg PO daily</td>
<td>300 mg/day</td>
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The initial dose escalation, first dose of each new level in the up-dosing schedule, and first maintenance dose must be administered under supervision of a qualified healthcare professional trained in the diagnosis and treatment of allergic diseases in a healthcare setting equipped to manage severe allergic reactions.

VI. Product Availability [Pending]

• Pull-apart capsules: 0.5 mg, 1 mg, 10 mg, 20 mg, 100 mg
• Foil-laminate sachets: 300 mg

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>Policy created</td>
<td>11.26.19</td>
<td>02.20</td>
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Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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