

Oral Immunotherapy (OIT) for the Treatment of Food Allergy

Policy Number: **M20201217222**
Effective Date: **2/2/2021**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: Internal External

Data Classification: Confidential Restricted Public

Applies to (Line of Business):

- Corporate (All)
- State Products, if yes which plan(s): MediSource; MediSource Connect; Child Health Plus; Essential Plan
- Medicare, if yes, which plan(s): MAPD; PDP; ISNP; CSNP
- Commercial, if yes, which type: Large Group; Small Group; Individual
- Self-Funded Services (*Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.*)

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes No

Purpose and Applicability:

To set forth Independent Health's medical necessary criteria for **oral immunotherapy (OIT)** for food allergy.

Policy:

Commercial and Self-Funded:

1. Oral immunotherapy is considered medically necessary when:
 - Delivered with a Food and Drug Administration (FDA) approved therapy. Currently Palforzia is FDA approved for the treatment of peanut allergy. Please refer to the Independent Health Pharmacy policy Palforzia (peanut [Arachis hypogaea] allergen-dnfp) powder, Policy No. M20200227015 for criteria.

2. Oral immunotherapy is considered experimental/investigational under any other circumstances due to lack of scientific published evidence.
3. Food challenge tests are covered once per suspected food allergen.
 - Any requests for additional food challenge tests for the same food allergy, suspected or known, require authorization from an Independent Health Medical Director. The provider request must be accompanied by specific documentation of the clinical indication requiring repeat testing.

Medicare Advantage:

Medicare Advantage utilizes the Commercial criteria above.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

Per New York State criteria, the addition of oral ingestion challenge testing may be medically necessary for those patients for whom a diagnosis of a food allergy or allergy to an oral drug has been inconclusive or inconsistent with clinical symptoms. In general, oral ingestion challenge testing should not be used as first-line testing for allergies. Oral ingestion challenge testing should only be performed in a carefully supervised allergy specialist setting, with emergency support immediately available.

Oral ingestion challenge testing is a covered service when considered medically necessary to confirm a positive in vivo/in vitro test result or to test for an allergic response to:

- Foods/ingested substances when in vivo/in vitro testing is inconclusive or inconsistent with clinical symptoms; or
- Oral medications when all the following are met:
 - Patient has a history of allergy to a specified drug; and
 - There is no effective alternative or equivalent drug; and
 - Patient requires treatment with the drug class.

Reminders:

- A complete physical exam and a detailed review of the patient's clinical history is expected prior to performing allergy testing.
- Testing should be performed only by licensed physicians who possess the competency to interpret results, manage possible adverse reactions and determine an appropriate course of treatment.
- Appropriate billing is the responsibility of all Medicaid providers and retrospective reviews may be conducted periodically through a Medicaid-funded utilization management contractor or the Office of the Medicaid Inspector General. The ordering physician must maintain sufficient documentation regarding the required patient history to clearly support the medical necessity of the test. In accordance with the New York Code of Rules and Regulations, 18 Nycrr 504.8 (a) (2); per 18 Nycrr 540.7 (a) (8), medical records must be maintained by providers for a period of not less than six years from the date of payment.

Background:

The current standard of care for food allergy treatment is avoidance of the allergen and treatment of anaphylaxis with auto-injectable epinephrine. The ultimate goal of food allergy therapy is to be able to consume the food freely without symptoms or fear of a reaction. This would require induction of permanent tolerance to the food, where the allergy reaction will not recur upon re-exposure after any

period of abstinence. Current available evidence indicates OIT is unlikely to induce permanent tolerance. An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

On January 31, 2020, the Food and Drug Administration approved the drug Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] to mitigate allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. This is the only FDA approved oral immunotherapy agent currently. Standardized protocols and/or clinical guidelines based on high quality clinical trials would be required before incorporating desensitization into clinical practice. At this time there is no evidence based clinical trial data supporting OIT, other than the treatment of peanut allergy with Palforzia.

Pre-Authorization Required? Yes No

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Desensitization refers to the improvement in food challenge outcomes after therapy and relies on ongoing exposure to the allergen.

Oral immunotherapy (OIT) refers to feeding an allergic individual an increasing amount of an allergen with the goal of increasing the threshold that triggers a reaction.

References

Related Policies, Processes and Other Documents

Palforzia (peanut [Arachis hypogaea] allergen-dnfp) powder, Policy No. M20200227015.

Non-Regulatory references

American Academy of Allergy, Asthma, and Immunology (AAAAI) [web site]. The Current State of Oral Immunotherapy (OIT) for the Treatment of Food Allergy. Reviewed: 2/4/20 Available at: <https://www.aaaai.org/tools-for-the-public/conditions-library/allergies/the-current-state-of-oral-immunotherapy> Accessed October 31, 2023,

Institute for Clinical Economic Review (ICER). Oral Immunotherapy and Viaskin®Peanut for Peanut Allergy: Effectiveness and Value. Published July 10, 2019. Available at: <https://collections.nlm.nih.gov/catalog/nlm:nlmuid-9918401083906676-pdf> Accessed October 31, 2023

Nowak-Węgrzyn, A. Oral immunotherapy for food allergy. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 31, 2023.)

PALISADE Group of Clinical Investigators, Vickery BP, Vereda A, Casale TB, et al. AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med. 2018 Nov 22;379(21):1991-2001.

Patrawala M, Shih J, Lee G, et al. Peanut Oral Immunotherapy: a Current Perspective. Curr Allergy Asthma Rep. 2020;20(5):14. Published 2020 Apr 20.

Vickery BP, Vereda A, Casale TB, et al. AR101 oral immunotherapy for peanut allergy. *New Engl J Med*. 2018;379(21):1991-2001.

Regulatory References

New York State Department of Health Medicaid Program [web site]. Medicaid Update. May 2016. Volume 32; Number 5, pp. 7-9. Available at:
https://www.health.ny.gov/health_care/medicaid/program/update/2016/may16_mu.pdf
 Accessed October 31, 2023.

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). Email response November 17, 2020.

United States Food and Drug Administration (FDA) [web site]. Package Insert – Palforzia. Available at:
<https://www.fda.gov/media/134838/download> Accessed October 31, 2023

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member’s contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes No

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
1/1/2023	Health Care Services	Revised
1/1/2022	Health Care Services	Reviewed