



Subject: Allergen Immunotherapy

Medical Policy #: 44.0 Original Effective Date: 05/26/2021
Status: Reviewed Last Annual Review Date: 05/28/2025

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans, or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Allergen Immunotherapy is defined as the repeated administration of specific allergens to patients **with IgE-mediated conditions** for the purpose of providing protection against allergic symptoms and inflammatory reactions associated with natural exposure to these allergens.

Allergen immunotherapy should be considered for patients who have demonstrable evidence of specific IgE antibodies to clinically relevant allergens. The decision to begin allergen immunotherapy might depend on a number of factors, including but not limited to patient's preference/acceptability, adherence, medication requirements, response to avoidance, and the adverse effects of medications.

The presence of IgE antibodies alone does not infer the need for immunotherapy. For example, the presence of IgE antibodies to an allergen not locally found, with no history or exposure or expectation of exposure, would not be considered to be clinically relevant.

Coverage Determination

Prior Authorization is not required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

Coverage is for Medicare, Medicaid and Commercial.

PHP follows CMS Local Coverage Determination, Allergen Immunotherapy (<u>L36240</u>) and see the related article LCA (<u>A56538</u>) for additional guidance.

PHP follows CMS, <u>Publication 100-02</u>, <u>Medicare Benefit Policy Manual</u>, <u>Chapter 15</u>, <u>section 50.4.4.1</u> for Allergen Supply: Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that <u>a reasonable supply of antigens</u> is <u>considered to be not more than a 12-month supply of antigens</u> that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient.

Frequency Limitations:

Medically Necessary:

Supervision (including preparation) and provision of up to 120 allergen/antigen preparations (units/doses) per rolling 12 months of subcutaneous allergy immunotherapy is considered medically necessary for the first year, this includes the build-up phase followed by a maintenance phase.

Supervision (including preparation) and provision of **120 allergen/antigen preparations (units/doses) or less per rolling 12 months** of subcutaneous allergy immunotherapy is considered **medically necessary** <u>after the first year</u> as *maintenance therapy*.

Not Medically Necessary:

Supervision (including preparation) and provision of greater than 120 allergen/antigen preparations (units/doses) per rolling 12 months of subcutaneous allergy immunotherapy is considered **not medically necessary** for the first year, including the build-up phase followed by a maintenance phase.

Supervision (including preparation) and provision of greater than 120 allergen/antigen preparations (units/doses) per rolling 12 months of subcutaneous allergy immunotherapy is considered **not medically necessary** after the first year as maintenance therapy.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description		
95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; immunotherapy one injection		
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections		
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single dose vial(s) (specify number of vials) The antigen is to be administered by another physician.		
95145	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom		
95146	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms		
95147	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms		
95148	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms		
95149	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms		
95165	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)		
95170	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; whole body extract of biting insect or other arthropod (specify number of doses)		
95180	Rapid desensitization procedure, each hour (eg, insulin, penicillin, equine serum)		

ICD-10 CODE	For covered ICD-10 codes, please see LCA Allergy Testing (A56538).			
 For the following CPT codes: 95115, 95117, 95144, 95145, 95146, 95147, 95148, 95149 and 95165, see the ICD-10 code listing under Group 1 For the following CPT code: 95170 see the ICD-10 code listing under Group 2: For the following CPT codes: 95180 see the ICD-10 code listing under Group 3. 				

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQ): Clinton White, MD

Senior Medical Director: <u>Jim Romero, MD</u> Medical Director: <u>Kresta Antillon, MD</u> Date Approved: 05/28/2025

References

- CMS, Local Coverage Determination, Novitas Solutions, LCD Allergen Immunotherapy (L36240), Revision history date: 03/31/2024, R8, Related article LCA (A56538), Revision history date: 03/31/2024, R8 [Cited 04/18/2025]
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.4.4.1 Antigens (Rev. 186, Issued: 04-16-14, Effective: 01-01 01, Implementation: 05-12-14), Accessed 04/18/2025

- 3. CMS IOM Publication100-02, *Medicare Benefit Policy Manual*, Chapter 15 Covered Medical and Other Health Services, 20.2 Physician Expense for Allergy Treatment, (Rev. 1, 10-01-03) *Accessed 04/18/2025*
- CMS IOM Publication 100-04, Medicare Claims Processing Manual, Chapter 12 Physicians/Nonphysician Practitioners, 200 - Allergy Testing and Immunotherapy, B. Allergy Immunotherapy, (Implementation: 08-25-2014) Accessed 04/18/2025

Publication History

- 05/26/2021 New policy. Reviewed by PHP Medical Policy Committee on 05/12/2021. The committee agreed to follow LCD Allergen Immunotherapy L36240 and the related article LCA (A56538) for all LOB. This policy developed to impose immunotherapy guideline such as schedule, frequency limitations and duration and/or length of treatment. The CPT codes listed in the policy will not require PA. ICD-10 codes will be configured using LCA Allergen Immunotherapy (A56538) for CPT codes 95115, 95117, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95199, 95170, and 95180. Look into configuring no payment after a 2-year period for all LOB, when there is no apparent clinical benefit.
- O5/25/2022 Annual review. Reviewed by PHP Medical Policy Committee on 05/11/2022. Upon further study of immunotherapy schedule, it seems CMS and other payers follow the practice parameter developed by the Joint Task Force, based upon this we will continue to follow CMS, LCD (L36240) and LCA (A56538). The coverage determination guideline language has been removed from policy and reformatted to only include LCD/LCA weblinks. Previous configuration will be re-configured to link the ICD-10 codes to CPT codes using the new revised LCA (A56538) for all LOB due to changes. Continue no PA requirement for 95115, 95117, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, and 95180.
- O5/24/2023 Annual review. Reviewed by PHP Medical Policy Committee on 04/21/2023. No change. Continue to follow LCD (L36240) and LCA (A56538). Continue no PA requirement. Update previous configuration to link the ICD-10 codes to CPT codes to link to the newly medically necessary ICD-10 codes per revision (R 5) of the LCA (A56538) for all LOB.
- O5/22/2024 Annual review. Reviewed by PHP Medical Policy Committee on 03-29-2024. For ALOB, continue to follow <u>LCD</u> Allergen Immunotherapy (L36240) and the related article LCA (A56538), without PA requirement, since codes are configured to medically necessary ICD-10 listed in LCA. LCD now allows Multiallergen subcutaneous immunotherapy, which used to be non-covered.
- O5/28/2025 Annual review. Reviewed by PHP Medical Policy Committee on 04/18/2025. For ALOB, continue to follow LCD Allergen Immunotherapy (L36240) and the related article LCA (A56538), without PA requirement, since codes are configured to medically necessary ICD-10 listed in LCA. Clarifying language added to outline frequency limitations, taking into account for both build up and maintenance phases, no more than 120 allergen/antigen preparations (units/doses) per rolling 12 months for the first year and less than 120 (units/doses) per rolling 12 months after the first year, based on limitations outlined by CMS. Configuration of 95165 will be applied for the frequency limitation mentioned in this review.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: Click here for Medical Policies

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded. PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to

support coverage.	. See the References section t	o view the source materials use	d to develop this resource