

## Reimbursement Policy

### Allergan Testing

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[POLICY DESCRIPTION](#) | [INDICATIONS AND/OR LIMITATIONS OF COVERAGE](#) | [APPLICABLE STATE AND FEDERAL REGULATIONS](#) | [APPLICABLE CPT/HCPCS PROCEDURE CODES](#) | [EVIDENCE-BASED SCIENTIFIC REFERENCES](#) |

#### I. Policy Description

Allergic disease is characterized by inappropriate or exaggerated immune reactions to foreign antigens (allergens) that are generally innocuous to most people, but when introduced into a genetically-predisposed individual, elicit a hypersensitivity reaction.<sup>1</sup> Hypersensitivity reactions can be classified into four types, two of which are associated with allergy, type I immediate immunoglobulin E (IgE) reactions and type IV T cell-mediated reactions.<sup>2</sup> Type I reactions involve the formation of IgE antibodies specific to the allergen. When the subject is re-exposed to that allergen, the allergen binds multiple IgE molecules, resulting in the release of an array of inflammatory mediators, including histamines, that precipitate the symptoms of allergic disease.<sup>1</sup>

Allergen testing in serum is designed to detect the presence of allergen-specific IgE. A positive test for allergen-specific IgE confirms the presence of the antibody only. Actual reactivity must be determined by history or supervised challenge.<sup>3</sup> Several diagnostic procedures have been developed to elicit and assess hypersensitivity reactions including epicutaneous, intradermal, patch, bronchial, exercise, and ingestion challenge tests.<sup>4</sup>

#### II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the "Applicable State and Federal Regulations" section of this policy document.

When limited to allergens chosen for testing based on an individual's history, physical examination, and environment, specific IgE in-vitro allergy testing (up to 20 allergen specific antibodies per year) **MEETS COVERAGE CRITERIA.**

- 1) In-vitro testing for total serum IgE **MEETS COVERAGE CRITERIA** in any of the following situations:
  - a) For individuals with moderate to severe asthma.
  - b) For individuals with signs or symptoms of allergic bronchopulmonary aspergillosis.
- 2) To monitor for allergy resolution in children and adolescents with an initial positive food allergen result(s), annual re-testing for the same food allergen(s) **MEETS COVERAGE CRITERIA.**
- 3) In the absence of a new clinical presentation, routine re-testing for allergies to the same allergens (except where specified above) **DOES NOT MEET COVERAGE CRITERIA.**
- 4) The antigen leukocyte antibody test (ALCAT) **DOES NOT MEET COVERAGE CRITERIA.**

## Reimbursement Policy

*The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.*

- 5) For individuals with signs or symptoms of allergies, basophil activation flow cytometry testing and in-vitro testing of IgG, IgA, IgM, and/or IgD **DO NOT MEET COVERAGE CRITERIA.**
- 6) In-vitro allergen testing using bead-based epitope assays (e.g., VeriMAP Peanut Dx) **DOES NOT MEET COVERAGE CRITERIA.**
- 7) For all situations, in-vitro testing using qualitative specific IgE multi-allergen screen that does not identify a specific allergen **DOES NOT MEET COVERAGE CRITERIA.**

### III. Applicable State and Federal Regulations

**DISCLAIMER:** If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <http://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

### IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
82784	Gammaglobulin (immunoglobulin); IgA, IgD, IgG, IgM, each
82785	Gammaglobulin (immunoglobulin); IgE
82787	Gammaglobulin (immunoglobulin); immunoglobulin subclasses (eg, IgG1, 2, 3, or 4), each
83516	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

## Reimbursement Policy

<b>86001</b>	Allergen specific IgG quantitative or semiquantitative, each allergen
<b>86003</b>	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
<b>86005</b>	Allergen specific IgE; qualitative, multiallergen screen (eg, disk, sponge, card)
<b>86008</b>	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
<b>88184</b>	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; first marker
<b>88185</b>	Flow cytometry, cell surface, cytoplasmic, or nuclear marker, technical component only; each additional marker
<b>0165U</b>	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy Proprietary test: VeriMAP™ Peanut Dx – Bead-based Epitope Assay Lab/Manufacturer: AllerGenis™ Clinical Laboratory
<b>0178U</b>	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction Proprietary test: VeriMAP™ Peanut Sensitivity - Bead Based Epitope Assay Lab/Manufacturer: AllerGenis™ Clinical Laboratory

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*Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.*

### V. Evidence-based Scientific References

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