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## Subject: Allergy Testing and Immunotherapy

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### DESCRIPTION:

Allergy is a form of exaggerated sensitivity or hypersensitivity, to a substance that is either inhaled, swallowed, injected, or comes in contact with the skin or eye. A reaction may be caused from exposure to pollens, dust, molds, mites, animal fur or dander, feathers, stinging insect venoms, foods, or drugs. The term allergy is used to describe situations where hypersensitivity results from heightened or altered reactivity of the immune system in response to external substances. Treatment typically consists of avoidance of the offending agent, medication or immunotherapy.

Injections of airborne or insect venom allergens are prepared for each person individually.

Allergy testing can be broadly subdivided into two methodologies:

In vivo testing – includes skin allergy testing (i.e., skin prick testing, skin scratch testing, intradermal testing, skin patch testing, and skin endpoint titration), bronchial provocation tests, and food challenges

In vitro testing – includes various techniques to test the blood for presence of specific IgE antibodies to a particular antigen (i.e., RAST and ELISA tests) and leukocyte histamine release test (LHRT), also referred to as basophil histamine release test.

Allergy immunotherapy is the process of administering progressively increasing doses of an allergen as treatment for a person who has demonstrated sensitivity through allergy testing. The purpose of immunotherapy is to relieve the allergic symptoms by decreasing the reaction to the specific antigen. This clinical intervention has been used over the past 80 years. Immunotherapy begins with injections of the allergen extract (allergen vaccine) in low doses, with gradual increasing doses once or twice weekly as immunity to the antigen develops. Upon reaching a maintenance dose, injections are decreased to every two to six weeks, and may continue for several years.

## POSITION STATEMENT:

### Allergy Testing

The following allergy tests **meet the definition of medical necessity** when performed by or under the direct supervision of a physician for the purpose of establishing a diagnosis of allergy disease:

- Direct nasal mucous membrane test
- Ingestion challenge test (Excluding ingestion challenge food testing; refer to next section below)
- Inhalation bronchial challenge testing with histamine, methacholine or similar compounds
- Intracutaneous (intradermal) tests, sequential and incremental with drugs, biologicals or venoms, immediate type reaction
- Intracutaneous (intradermal) tests, sequential and incremental with drugs, with allergenic extracts for airborne allergens, immediate type reaction
- Intracutaneous (intradermal) tests with allergenic extracts (allergen vaccine), immediate type reaction (i.e., serial endpoint titration/SET)
- Intracutaneous (intradermal) tests with allergenic extracts (allergen vaccine), delayed type reaction, including reading
- Ophthalmic mucous membrane test
- Patch (application) tests with any membrane
- Percutaneous (scratch, puncture, prick) tests with allergenic extracts (allergen vaccine), immediate type reaction
- Percutaneous (scratch, puncture, prick) tests sequential and incremental, with drugs, biologicals or venoms, immediate type reaction
- Photopatch tests
- Provocative testing (e.g., Rinkel test)
- In vitro testing for allergen specific IgE, which includes:
  - ELISA (enzyme linked immunosorbent assay)
  - FAST (Fluorescent allergosorbent test)
  - IP (Immuno-peroxidase test)
  - MAST (Multiple thread allergosorbent test)
  - RAST (Radioallergosorbent test)
  - PRIST (Paper radioimmunosorbent test)
  - CAP assay

Aspirin desensitization **meets the definition of medical necessity** for aspirin sensitive individuals who:

- Require administration of aspirin or aspirin-like drugs, **OR**
- Are unable to avoid aspirin or aspirin-like drugs, **AND**

- **ONE** of the following:
  - Asthma that is poorly controlled
  - Sinus disease with recurrent nasal polyps
  - Require aspirin therapy for primary or secondary prevention of cardiovascular events
  - A chronic inflammatory condition (e.g., arthritis) requiring aspirin or NSAID therapy
  - Antiphospholipid antibodies during pregnancy

The following types of allergy testing are considered **experimental or investigational** as controlled studies have failed to demonstrate the value of these tests for the diagnosis of allergies in clinical practice. This is not an all-inclusive list.

- Administration of allergy immunotherapy outside of a medical facility (e.g., home administration)
- Antigen leukocyte cellular antibody (ALCAT) (automated food allergy testing)
- Applied kinesiology or Nambudripad's allergy elimination test (NAET) (i.e., muscle strength testing or measurement after allergen ingestion)
- Candidiasis test
- Chemical analysis of body tissue (eg, hair)
- Chlorinated pesticides (serum)
- Complement antigen testing (total or components)
- Cytokine and cytokine receptor assay
- Cytotoxic testing for food, environmental or clinical ecological allergy testing (Bryans Test, ACT)
- Electrodermal testing or electrodermal acupuncture
- Food immune complex assay (FICA)
- Ingestion challenge food testing for diagnosing rheumatoid arthritis, depression, or respiratory disorders not associated with anaphylaxis or similar systemic reactions
- Intracutaneous and subcutaneous provocative and neutralization testing for food allergies
- Immune complex assay
- Iridology
- Leukocyte histamine release test (LHRT)/basophil histamine release test
- Lymphocytes (B or T subsets)
- Lymphocyte function assay
- Mediator release test (MRT)
- Prausnitz-Kustner or P-K testing (passive cutaneous transfer test)
- Pulse test (pulse response test, reaginic pulse test)
- Rebeck skin window test

- Sage Complement Antigen Test
- Testing for multiple chemical sensitivity syndrome (a.k.a., idiopathic environmental intolerance (IEI), clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease)
- Urine autoinjection (autogenous urine immunization)

Routine allergy re-testing **does not meet the definition of medical necessity**.

**Environmental therapy**, also known as idiopathic environmental intolerance therapy or clinical ecology treatment, **does not meet the definition of medical necessity** as there is insufficient peer-reviewed medical literature to support these therapies as being any more effective than the standard care for treatment.

This method of therapy may include the following:

- Aerobic exercise therapy
- Alteration of the individual's household environment
- Environmental care units
- Neutralizing therapy of chemical and food extracts
- Nutritional therapy

### **Allergen Immunotherapy**

Allergen immunotherapy by intradermal or subcutaneous injection **meets the definition of medical necessity** when administered for the treatment of individuals demonstrating hypersensitivity to specific antigens that cannot be managed by medications or avoidance.

Allergen immunotherapy services may include one or more of the following:

- Individual evaluation related to the supply or administration of the allergenic extract (allergen vaccine)
- Supplies (needles, syringes, diluents)
- Monitoring the physical status of the individual during administration of the extract (allergen vaccine.)

Immunotherapy using sublingual drops (also known as sublingual antigen extract drop immunotherapy, sublingual liquid immunotherapy, aqueous extract products) is considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

**NOTE:** For coverage information on sublingual immunotherapy (SLIT) using a specific drug (e.g., Oralair<sup>®</sup>, Grastek<sup>®</sup>, Ragwitek<sup>®</sup>, Odactra<sup>®</sup>), please refer to the member contract pharmacy benefits.

## BILLING/CODING INFORMATION:

### CPT Coding for allergy testing:

0165U	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0178U	Peanut allergen specific quantitative assessment of multiple epitopes using enzyme linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction
86001	Allergen specific IgG quantitative or semiquantitative, each allergen <b>(investigational)</b>
86003	Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
86005	Allergen specific IgE; quantitative, multi-allergen screen (e.g., disk, sponge, card)
86008	Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests
95027 *	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests
95044	Patch or application test(s) (specify number of tests)
95052	Photo patch test(s) (specify number of tests)
95056	Photo tests
95060	Ophthalmic mucous membrane tests
95065	Direct nasal mucous membrane test
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds
95076 *	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing
95079 *	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); each additional 60 minutes of testing (List separately in addition to code for primary procedure)

### CPT Coding for Allergy Immunotherapy:

95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection
95117	Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections
95120	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single injection
95125	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 or more injections
95130	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; single stinging insect venom
95131	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 2 stinging insect venoms
95132	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 3 stinging insect venoms
95133	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 4 stinging insect venoms
95134	Professional services for allergen immunotherapy in the office or institution of the prescribing physician or other qualified health care professional, including provision of allergenic extract; 5 stinging insect venoms
95144	Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy, single or multiple antigens, single dose vials (specify number of vials)
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 (specify number of doses); whole body extract of biting insect or other arthropod (specify number of doses)
95180	Rapid desensitization procedure, each hour (e.g., insulin, penicillin, equine serum)

## REIMBURSEMENT INFORMATION:

Reimbursement for allergy testing services includes the following components:

- Supplies (e.g., sterile diluents, syringes, needles)
- Monitoring the physical status of the individual during testing
- Observation, recording, and interpretation of the test results

Reimbursement for allergy testing is based on the number of each type of test performed by the same physician and is subject to the following limitations when the above coverage criteria are met:

### Limitations:

CPT Code:	Type of Test:	Limited To:
86005	Allergen specific IgE; qualitative, multiallergen	1 per year
95004	Percutaneous tests (scratch, puncture, prick) with immediate type reaction	400 in 12 months
95017	Allergy testing with venoms; any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal) testing	120 in 12 months
95018	Allergy testing with drugs and biologicals; any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal) testing	120 in 12 months
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction	120 in 12 months
95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction	120 in 12 months
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction	120 in 12 months
95044	Patch or application test(s)	200 in 12 months
95052	Photo patch test(s)	200 in 12 months
95056	Photo tests	200 in 12 months
95060	Ophthalmic mucous membrane tests	48 in 12 months
95065	Direct nasal mucous membrane test	48 in 12 months
95070, 95071	Inhalation bronchial challenge testing	48 in 12 months
95076 (95079 is an add-on code that is not reported alone)	Ingestion challenge test	4 per year total 1 per year for any given food

The AAAAI practice guidelines make the following recommendations regarding immunotherapy frequency and duration:

- The build-up phase (also called up dosing phase, induction phase or dose-increase phase) involves receiving injections with increasing amounts of allergen, and generally ranges from 1 to 3 times per week. The duration of this phase depends on the frequency of the injections but generally ranges from 3 to 6 months (at a frequency of 2 times and 1 time per week, respectively).
- Cluster immunotherapy is an accelerated build-up schedule that entails administering several injections at increasing doses (generally 2-3 per visit) sequentially in a single day of treatment on nonconsecutive days.
- Rush immunotherapy is an accelerated immunotherapy build-up schedule that entails administering incremental doses of allergens at intervals varying between 15 and 60 minutes over 1 to 3 days.
- The maintenance dose or effective therapeutic dose is the dose that provides therapeutic efficacy without significant adverse local or systemic reactions; it may not be the initially calculated projected effective dose.
- The maintenance phase begins when the effective therapeutic dose is achieved; intervals between injections can be progressively increased as tolerated to 4 – 8 weeks for venom, and 2 to 4 weeks for inhalants.
- Venom immunotherapy (VIT) injections generally are given at weekly intervals.
- VIT intervals between maintenance dose injections can increase to 4 weeks the first year of VIT and eventually to every 6 – 8 weeks during subsequent years.
- Clinical improvement is usually observed within one (1) year after the individual reaches maintenance or effective therapeutic dose.
- The decision to continue or stop therapy should be made after 3 – 5 years.
  - Consider discontinuing VIT after 3 – 5 years.
  - The duration of fire ant immunotherapy has not been clearly established, but most allergists recommend continuing therapy 4 – 5 years.

Reimbursement for **allergy immunotherapy** is based on the number of procedures performed and is subject to the limitations below:

**Limitations:**

CPT Code	Procedure	Limited to
95115, 95117**	Administration of extract (allergen vaccine)	152 total injections within 12 months
95120, 95125	Allergenic extract (allergen vaccine) including administration	100 total doses within 12 months
95144	Allergenic extract, single dose vials (specify number of vials)	156 doses within 12 months (specify number of vials)



95165	Allergenic extract, single or multiple antigens (specific number of doses)	156 total doses within 12 months
95130 – 95134	Stinging insect venom, including administration	52 total doses within 12 months
95145 – 95149, 95170	Stinging insect venom	52 total doses within 12 months OR 40 total doses within 3 months for rapid desensitization
95180	Rapid desensitization	4 hours for a specific substance (excluding aspirin)
No specific code	Aspirin desensitization	12 hours per year

Allergy testing or immunotherapy services in excess of the above limitations are subject to medical review of documentation supporting medical necessity. The following information may be required documentation to support medical necessity: physician history and physical, care provider notes, and all laboratory studies.

#### LOINC Codes:

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician initial assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Allergy tests	18716-1	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Laboratory studies (i.e., ELISA, RAST, PRIST, Mast)	26436-6	18805-2	Include all data of the selected type that represents observations made

			six months or fewer before starting date of service for the claim.
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## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

### Medicare Advantage:

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date and are located at cms.gov:

Antigens Prepared for Sublingual Administration (110.9)

Food Allergy Testing and Treatment (110.11)

Challenge Ingestion Food (110.12)

Cytotoxic Food Tests (110.13)

The following Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date and are located at cms.gov:

Allergy Testing (L33261)

Allergen Immunotherapy (L37800)

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#)

## DEFINITIONS:

**ALCAT:** antigen leukocyte cellular antibody) automated food allergy testing; is reported to identify food sensitivity by using a modified Coulter Counter linked to a computer program to measure the change in white blood cells incubated with purified food and mold extract.

**Allergen:** any substance that indicates a state of, or brings on, manifestations of allergy; an antigenic substance capable of producing immediate-type hypersensitivity.

**Allergenic extract (allergen vaccine):** an extract (allergen vaccine) of allergenic components from a crude preparation of an allergen (e.g., weed, grass, mite, animal dander) used for diagnostic skin testing or for immunotherapy (hyposensitization) of allergy.

**Allergy:** an over-reaction of the body's immune system, against particular substances and particles (allergens, antigens) such as pollen, animal dander, dust, insect particles.

**Antigen:** the specific particle that one is allergic to, such as the specific part of pollen.

**Antihistamine:** drug that blocks the allergic reaction.

**Asthma:** a reversible obstructive lung disorder characterized by increased responsiveness of the airways; inflammation and irritation of the airways that may cause wheezing, sneezing, coughing, or shortness of breath.

**Bronchial challenge:** see provocation test; involves the inhalation of agents that trigger respiratory responses (i.e., drugs causing airway constriction, antigens and chemical sensitizers usually related to occupational breathing problems).

**Conjunctival challenge:** see provocation test; small amount of antigen is applied to the lower conjunctival sac.

**Custer immunotherapy:** an accelerated build-up schedule that entails administering several injections at increasing doses (generally 2 – 3 per visit) sequentially in a single day of treatment on nonconsecutive days. The maintenance dose is generally achieved more rapidly than with a conventional (single injection per visit) build-up scheduled (generally within 4 – 8 weeks).

**Cytotoxic testing:** for determining sensitivity to foods believed to cause asthma, arthritis, constipation, diarrhea hypertension, obesity, stomach disorders, and many other conditions; used in the 1980's; controlled clinical studies have failed to demonstrate effectiveness or reliability.

**ELISA (enzyme linked immunosorbent assay):** an in vitro assay for allergen specific IgE antibodies in serum, indicating an allergy to the substance.

**FAST (fluorescent allergosorbent test):** an in vitro assay using a fluoregenic detection system that looks for allergen specific IgE antibodies in serum, indicating an allergy to the substance.

**Food challenge test:** used to confirm or diagnose IgE- mediated hypersensitivity to specific foods, food additives and preservatives (metabisulfite). Increasing amounts of the suspected food allergen is ingested every 15 – 20 minutes for 2 hours or until a reaction occurs or the amount is higher than that expected to produce a reaction. One food item is tested per day.

**Idiopathic environmental intolerance:** The original term, clinical ecology, was replaced by the term multiple chemical sensitivity (MCS). Most recently, it has been replaced by the term idiopathic environmental intolerance, a term reflecting the uncertain nature of the condition and its relationship to chemical exposure. The central focus of the condition is the fact that the individual describes recurrent, nonspecific symptoms referable to multiple organ systems that the sufferers believe are provoked by exposure to low levels of chemical, biologic, or physical agents. The most common environmental exposures include perfumes and scented products, pesticides, domestic and industrial solvents, new carpets, car exhaust, gasoline and diesel fumes, urban air pollution, cigarette smoke, plastics, and formaldehyde. Certain foods, food additives, drugs, electromagnetic fields, and mercury in dental fillings have also been reported as triggering events. However symptoms do not bear any relationship to established toxic effects of the specific chemical and occur at concentrations far below those expected to elicit toxicity.

**Immunotherapy:** allergy injection therapy; the process of injecting small amounts of substances causing the allergy reaction; over a period of time, doses are progressively increased until the body adjusts to

the substance, or becomes desensitized; other treatments include avoidance of the substance or taking medications such as antihistamines to block the allergic reaction.

**In vitro testing:** within a glass or test tube; in an artificial environment.

**In vivo testing:** used to identify allergic substances that are responsible for producing diseases such as asthma, allergic rhinitis, eczema, urticaria, anaphylaxis, and gastrointestinal reactions.

**In vivo:** within the living body.

**Intradermal or Intracutaneous test:** a small amount (.001 to .05 ml) of antigen extract (allergen vaccine) is injected into the skin with a disposable syringe attached to a 26- to 30- gauge needle or with a tuberculin type syringe; a reaction is recorded 15 – 30 minutes after application. This type of skin testing is more suitable to individuals with lower skin sensitivity or for antigens with lower potency. Because of the added risk of adverse systemic reactions due to the larger volume of antigen extract (allergen vaccine) used, these tests are typically performed on the upper arm or forearm rather than the back, to allow application of a tourniquet if necessary, and are performed in a setting with staff capable of handling adverse reactions and emergencies.

**IP (Immuno-peroxidase test):** an in vitro assay for allergen specific IgE antibodies in serum, indicating an allergy to the substance.

**LEAP:** Lifestyle Eating and Performance disease management program (Don Self & Associates, Inc.) is based on the theory that symptoms of irritable bowel syndrome and other certain conditions are caused by reactions to specific foods and food additives. The program includes individual selection tools, a self-directed stress management program, and assessment tools for determining outcomes.

**MAST (multiple thread allergosorbent test):** an in vitro assay using an enzymatic detection system that looks for allergen specific IgE antibodies in serum, indicating an allergy to the substance.

**Mediator release test (MRT):** primarily used to detect intolerance to foods and additives in individuals with irritable bowel syndrome. Also used in individuals with chronic fatigue syndrome, metabolic conditions (e.g., diabetes, obesity), gastrointestinal disorders (e.g., gastroesophageal reflux disease, chronic ulcerative colitis, and Crohn's disease), neurologic disorders (e.g., migraine headaches, cluster headaches), rheumatologic disorders (inflammatory arthritis, arthralgias, fibromyalgia), otolaryngologic disorders (e.g., perennial rhinitis, chronic sinusitis, chronic otitis media with effusion), dermatologic conditions (e.g., eczema, urticaria, dermatitis), and in individuals with behavioral conditions (e.g., attention deficit disorder, hyperactivity, frequent mood swings, inability to concentrate). This test measures the aggregate release of inflammatory mediators from the individual's immunocytes in vitro after exposure to specific foods and food additives. The results of the mediator release test have been used to design an individual -specific diet to treat irritable bowel syndrome by avoiding foods and additives that trigger significant inflammatory mediator release.

**Nasal challenge:** see provocation test.

**Patch (application) test:** antigen is impregnated into a small piece of gauze or filter paper disc and applied to a strip of aluminum foil or placed within an 8 mm diameter aluminum device (Finn chamber) and applied to the skin and held in place with tape (a test system known as the TRUE test uses multiple

antigens incorporated into a gel delivery system); reactions are observed and recorded at 48 hours after application and may be read again 1 – 5 days after the first reading.

**Prick or puncture test:** a drop of antigen is placed directly on the skin then gently pricked through with a sharp instrument (needle, lancet, or specially designed plastic device) at a 45 – 60 degree angle (prick test) or 90 degree angle (puncture); reactions are recorded at 15 – 20 minutes after application.

**PRIST (paper radioimmunosorbent test):** an in vitro assay for allergen specific IgE antibodies in serum, indicating an allergy to the substance.

**Proteolytic enzyme:** when preparing mixtures of allergen extracts, the prescribing physician must take into account the cross-reactivity of allergen extracts and the potential for allergen degradation caused by proteolytic enzymes (breakdown of proteins).

**Provocation test:** challenge test performed to duplicate the individual's main symptoms or signs by controlled exposure to a suspected antigen; can be delivered by ingestion (food, oral challenge), inhalation (bronchial challenge), or by direct application to the mucosal membrane of nares (nasal challenge) or conjunctiva (conjunctival challenge).

**RAST (radio-allergo-sorbent test):** an in vitro assay for allergen specific IgE antibodies in serum; designed to aid in the diagnosis of IgE-mediated disorders and in the formulation of allergen immunotherapy.

**Rhinitis:** inflammation of the nasal mucosa.

**Rush immunotherapy:** an accelerated immunotherapy build-up schedule that involves administering incremental doses of allergen at intervals varying between 15 and 60 minutes over 1 – 3 days until the targeted therapeutic dose is achieved. A rush immunotherapy schedules for inhalant allergens can be associated with a greater risk of systemic reactions, particularly in high-risk individuals (e.g., those with markedly positive prick/puncture test responses), and premedication with antihistamines and corticosteroids appears to reduce the risk associated with rush immunotherapy.

**SAGE:** a cellular assay that tests for delayed food sensitivity; the SAGE method uses whole blood, rather than serum, and tests simultaneously for multiple pathways.

**Scratch tests:** the skin is superficially scratched with a blunt scarifying device in such a way as to prevent excessive bleeding; a drop of antigen extract (allergen vaccine) is then applied to the scratch; antigen and control sites are recorded 20 minutes after application.

**Skin test:** applying a small amount of an antigen extract (allergen vaccine) directly to the skin either by intradermal tests or by epicutaneous, epidural, or percutaneous tests (scratch, prick, puncture, and patch tests).

## **RELATED GUIDELINES:**

[Peanut \(\*Arachis hypogaea\*\) Allergen Powder-dnfd \(Palforzia\), 09-J3000-69](#)

## **OTHER:**

None applicable.

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### COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 06/23/22.

### GUIDELINE UPDATE INFORMATION:

05/15/01	Medical Coverage Guideline Reformatted and Revised.
01/01/02	HCPCS coding changes.
01/01/03	HCPCS coding changes.
05/15/03	Reviewed; limitation changed for allergenic extract.
05/15/04	Scheduled review; added "mediator release test" to list of non-covered services; formatting revisions.
05/15/05	Scheduled review; no change in coverage statement.
10/15/05	Revision consisting of adding information regarding SAGE food allergy test.
05/15/06	Scheduled review: added investigational statement for sublingual immunotherapy for allergies and added additional tests and immunotherapies for idiopathic environmental illness; updated references.
09/15/06	Revision consisting of adding 83516, 83518, 83519, 83520, and 86005 to the list of allergy tests.
01/01/07	Annual HCPCS coding update (deleted 95078.)
05/15/07	Scheduled review; reformatted guideline; no change in coverage statement.
01/01/08	Annual HCPCS coding update: descriptor revisions for codes 95004, 95024, and 95027.
07/15/08	Scheduled review; no change in position statement; updated references.
01/01/09	Annual HCPCS coding update: revised descriptors for 95010 and 95015.
01/09/09	Revisions consisting of addition of criteria regarding IgG food allergy testing; reference added.
11/15/09	Scheduled review; no position statement changes; medical society information added regarding mixing of allergen extracts; reimbursement limitations revised; definitions added; references updated.
01/01/10	Annual HCPCS coding update: revised descriptors for 83516, 83518, 83519, and 83520.
04/15/10	Revision to Billing/Coding and Reimbursement sections regarding 83516, 83518, and 83519.
12/15/10	Scheduled review; Position Statement unchanged; added information regarding LEAP program; coding section revised; related ICD-10 codes added; references updated; formatting changes.
04/15/11	Revision to Reimbursement section of the guideline regarding allergen extracts.
07/15/11	Revision; formatting changes.
10/01/11	Revision to Reimbursement section.

12/15/11	Revisions to Billing/Coding (deleted code 83520) and Reimbursement sections.
03/15/12	Revision; Reimbursement section updated.
11/15/12	Annual review; position statement reformatted, references updated, formatting changes.
01/01/13	Annual HCPCS coding update: added 95017, 95018, 95076, and 95079; revised descriptors for 95004, 95027, 95120, 95125, 95130, 95131, 95132, 95133, and 95134; deleted 95010, 95015, and 95075.
11/15/13	Annual review; position statements unchanged; Program Exceptions section updated; references updated.
11/15/14	Annual review; position statement regarding sublingual immunotherapy revised; references updated; formatting changes.
06/15/16	Added CPT code 86001.
08/15/17	Scheduled review. Deleted "In vitro testing for allergen specific IgG" from the list of testing considered medically necessary. Added additional testing considered experimental or investigational. Deleted coverage statement for sublingual immunotherapy (SLIT) using Oralair®, Grastek®, or Ragwitek®. Revised Reimbursement Information section. Updated references. Reformatted guideline.
11/10/17	Revision: Added note regarding coverage of sublingual immunotherapy.
01/01/18	Annual CPT/HCPCS coding update: added 86008; revised 86003, 86005.
03/15/18	Revision: added criteria for aspirin desensitization; revised Reimbursement Information section; updated references.
08/15/18	Unscheduled review. Maintained position statement and updated references.
11/15/19	Revision. Added (E/I) coverage statement for sublingual immunotherapy antigen drops. Updated references.
04/01/20	Quarterly CPT/HCPCS coding update: added 0165U.
07/01/20	Quarterly CPT/HCPCS coding update: added 0178U; revised code descriptor 0165U.
08/15/20	Scheduled review. Revised list of allergy tests considered E/I. Updated references.
01/01/21	Annual CPT/HCPCS coding update. Revised 95070; deleted 95071.
08/15/21	Revision. Updated list of services considered environmental therapy.
07/15/22	Scheduled review. Added non-coverage statement for allergy immunotherapy administered outside a medical facility. Updated references.
05/22/23	Update to Program Exceptions section.