Subject: Allergy Testing and Immunotherapy

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 the patient 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:

Certificate of Medical Necessity

Submit a completed Certificate of Medical Necessity (CMN) along with your request to expedite the medical review process.

1. Click the link Allergy Testing under Certificates of Medical Necessity in the side navigation of this page to access the form.
2. Complete all fields on the form thoroughly.
3. Print and submit a copy of the form with your request.

Note: Florida Blue regularly updates CMNs. Ensure you are using the most current copy of a CMN before submitting to Florida Blue.

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
• Photo tests
• Provocative testing (e.g., Rinkel test)
• In vitro testing for allergen specific IgE, which includes:
  o ELISA (enzyme linked immunosorbent assay)
  o FAST (Fluorescent allergosorbent test)
  o IP (Immuno-peroxidase test)
  o MAST (Multiple thread allergosorbent test)
  o RAST (Radioallergosorbent test)
  o PRIST (Paper radioimmunosorbent test)
  o 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:
  o Asthma that is poorly controlled
  o Sinus disease with recurrent nasal polyps
  o Require aspirin therapy for primary or secondary prevention of cardiovascular events
  o A chronic inflammatory condition (e.g., arthritis) requiring aspirin or NSAID therapy
  o 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.
• Allergen specific IgG or IgG subclass measurement, any allergen [including IgG assays and IgG subclass assays for testing food or environmental allergies (e.g., Immuno 1 Bloodprint™; AllergySmarts Food Intolerance Testing; foodSCAN IgG ELISA Food Intolerance Test]
• Alpha gal allergy (meat allergy) testing
• Antigen leukooyte cellular antibody (ALCAT) (automated food allergy testing)
• Basophil activation test (BAT)
• Candidiasis test (serum, saliva, stool)
• Chlorinated pesticides (serum)
• Chronic urticaria index testing
• Complement antigen testing (total or components)
- Cytokine and cytokine receptor assay
- Cytotoxic testing for food, environmental or clinical ecological allergy testing
- Electrodermal testing or electrodermal acupuncture
- Food immune complex assay (FICA)
- Food specific IgG antibodies
- Hair analysis
- Idiopathic environmental intolerance – any lab tests designed to affirm the diagnosis of idiopathic environmental intolerance
- 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
- Iridology
- Leukocyte antibodies testing
- Lymphocyte subset counts
- Lymphocyte function assay
- Mediator release test (MRT) or the LEAP Program, in which the Mediator Release Test (MRT) is used to identify "delayed food allergies"; treatment involves dietary manipulation and possibly supplements and/or herbs
- Muscle strength testing or measurement (kinesiology) after allergen ingestion
- Nutritional assessments, including intracellular analysis of micronutrients
- Prausnitz-Kustner or P-K testing (passive cutaneous transfer test)
- SAGE testing for food delayed sensitivity
- Sublingual provocative testing for food allergies
- Urine autoinjection (autogenous urine immunization)

Environmental therapy, also known as idiopathic environmental intolerance 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 patient's household environment
- Avoidance therapy
- Elimination diet
- Environmental care units
- IVIG
- Massages
• Neutralizing therapy of chemical and food extracts
• Nutritional therapy
• Physical therapy
• Rotation diets
• Vaccine therapy

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

**Allergen Immunotherapy**

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

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

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

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

**BILLING/CODING INFORMATION:**

**CPT Coding for allergy testing:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>86001</td>
<td>Allergen specific IgG quantitative or semiquantitative, each allergen (investigational)</td>
</tr>
<tr>
<td>86003</td>
<td>Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each</td>
</tr>
<tr>
<td>86005</td>
<td>Allergen specific IgE; quantitative, multi-allergen screen (e.g., disk, sponge, card)</td>
</tr>
<tr>
<td>86008</td>
<td>Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each</td>
</tr>
<tr>
<td>95004</td>
<td>Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests</td>
</tr>
<tr>
<td>95017</td>
<td>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</td>
</tr>
<tr>
<td>95018</td>
<td>Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals,</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>95024</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report by a physician, specify number of tests</td>
</tr>
<tr>
<td>95027*</td>
<td>Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests</td>
</tr>
<tr>
<td>95028</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests</td>
</tr>
<tr>
<td>95044</td>
<td>Patch or application test(s) (specify number of tests)</td>
</tr>
<tr>
<td>95052</td>
<td>Photo patch test(s) (specify number of tests)</td>
</tr>
<tr>
<td>95056</td>
<td>Photo tests</td>
</tr>
<tr>
<td>95060</td>
<td>Ophthalmic mucous membrane tests</td>
</tr>
<tr>
<td>95065</td>
<td>Direct nasal mucous membrane test</td>
</tr>
<tr>
<td>95070</td>
<td>Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with histamine, methacholine, or similar compounds</td>
</tr>
<tr>
<td>95071</td>
<td>Inhalation bronchial challenge testing (not including necessary pulmonary function tests); with antigens or gases, specify</td>
</tr>
<tr>
<td>95076*</td>
<td>Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug or other substance); initial 120 minutes of testing</td>
</tr>
<tr>
<td>95079*</td>
<td>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)</td>
</tr>
</tbody>
</table>

**CPT Coding for Allergy Immunotherapy:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>95115</td>
<td>Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection</td>
</tr>
<tr>
<td>95117</td>
<td>Professional services for allergen immunotherapy not including provision of allergenic extracts; 2 or more injections</td>
</tr>
<tr>
<td>95120</td>
<td>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;</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>95125</td>
<td>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</td>
</tr>
<tr>
<td>95130</td>
<td>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</td>
</tr>
<tr>
<td>95131</td>
<td>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</td>
</tr>
<tr>
<td>95132</td>
<td>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</td>
</tr>
<tr>
<td>95133</td>
<td>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</td>
</tr>
<tr>
<td>95134</td>
<td>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</td>
</tr>
<tr>
<td>95144</td>
<td>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)</td>
</tr>
<tr>
<td>95145</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); single stinging insect venom</td>
</tr>
<tr>
<td>95146</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 2 single stinging insect venoms</td>
</tr>
<tr>
<td>95147</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 3 single stinging insect venoms</td>
</tr>
<tr>
<td>95148</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 4 single stinging insect venoms</td>
</tr>
<tr>
<td>95149</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 5 single stinging insect venoms</td>
</tr>
<tr>
<td>95165</td>
<td>Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy (specify number of doses); 6 single stinging insect venoms</td>
</tr>
</tbody>
</table>
immunotherapy; single or multiple antigens (specify number of doses)

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Type of Test</th>
<th>Limited To</th>
</tr>
</thead>
<tbody>
<tr>
<td>95170</td>
<td>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)</td>
<td></td>
</tr>
<tr>
<td>95180</td>
<td>Rapid desensitization procedure, each hour (e.g., insulin, penicillin, equine serum)</td>
<td></td>
</tr>
</tbody>
</table>

**REIMBURSEMENT INFORMATION:**

Reimbursement for allergy testing services includes the following components:

- Supplies (e.g., sterile diluents, syringes, needles)
- Monitoring the physical status of the patient 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:**

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Type of Test</th>
<th>Limited To</th>
</tr>
</thead>
<tbody>
<tr>
<td>86005</td>
<td>Allergen specific IgE; qualitative, multiallergen</td>
<td>1 per year</td>
</tr>
<tr>
<td>95004</td>
<td>Percutaneous tests (scratch, puncture, prick) with immediate type reaction</td>
<td>400 in 12 months</td>
</tr>
<tr>
<td>95017</td>
<td>Allergy testing with venoms; any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal) testing</td>
<td>120 in 12 months</td>
</tr>
<tr>
<td>95018</td>
<td>Allergy testing with drugs and biologicals; any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal) testing</td>
<td>120 in 12 months</td>
</tr>
<tr>
<td>95024</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction</td>
<td>120 in 12 months</td>
</tr>
<tr>
<td>95027</td>
<td>Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction</td>
<td>120 in 12 months</td>
</tr>
<tr>
<td>95028</td>
<td>Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction</td>
<td>120 in 12 months</td>
</tr>
</tbody>
</table>
The AAAAI practice guidelines make the following recommendations regarding immunotherapy frequency and duration:

- The build-up phase (also called updosing 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 does 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 patient 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:**

<table>
<thead>
<tr>
<th>CPT Code:</th>
<th>Procedure:</th>
<th>Limited to:</th>
</tr>
</thead>
<tbody>
<tr>
<td>95115, 95117**</td>
<td>Administration of extract (allergen vaccine)</td>
<td>152 total injections within 12 months</td>
</tr>
<tr>
<td>95120, 95125</td>
<td>Allergenic extract (allergen vaccine) including administration</td>
<td>100 total doses within 12 months</td>
</tr>
<tr>
<td>95144</td>
<td>Allergenic extract, single dose vials (specify number of vials)</td>
<td>156 doses within 12 months (specify number of vials)</td>
</tr>
<tr>
<td>95165</td>
<td>Allergenic extract, single or multiple antigens (specific number of doses)</td>
<td>156 total doses within 12 months</td>
</tr>
<tr>
<td>95130 – 95134</td>
<td>Stinging insect venom, including administration</td>
<td>52 total doses within 12 months</td>
</tr>
<tr>
<td>95145 – 95149, 95170</td>
<td>Stinging insect venom</td>
<td>52 total doses within 12 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40 total doses within 3 months for rapid desensitization</td>
</tr>
<tr>
<td>95180</td>
<td>Rapid desensitization</td>
<td>4 hours for a specific substance (excluding aspirin)</td>
</tr>
<tr>
<td>No specific code</td>
<td>Aspirin desensitization</td>
<td>12 hours per year</td>
</tr>
</tbody>
</table>

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

**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 fcso.com:

Allergy Tests (L33261)
Allergen Immunotherapy (L33804)

**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 schedule (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 patient 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**: within a glass or test tube; in an artificial environment.

**In vivo allergy tests**: 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 patients 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 patient 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 patients with irritable bowel syndrome. Also used in patients 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 patients 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 patient’s immunocytes in vitro after exposure to specific foods and food additives. The results of the mediator release test have been used to design a patient-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 patient’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 patients (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:** None applicable.

**OTHER:**
Other terms describing allergy immunotherapy or allergy testing:

Allergy desensitization
Allergy shots

Hyposensitization

Specific antigen immunotherapy (SIT)

Other terms describing cytotoxic testing:

Cell Mediated Food Sensitivity

Food Intolerance Test (FIT)

Leukooyte-Antigen Sensitivity Testing (LAST)

Leukooytotoxic

Metabolic Intolerance Test (MIT)

Neutrophile Degranulation

Polymophonuclear Degranulation

White Cell Degranulation

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**COMMITTEE APPROVAL:**
This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 07/26/18.

**GUIDELINE UPDATE INFORMATION:**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>05/15/01</td>
<td>Medical Coverage Guideline Reformatted and Revised.</td>
</tr>
<tr>
<td>01/01/02</td>
<td>HCPCS coding changes.</td>
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<td>Description</td>
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<tr>
<td>01/01/03</td>
<td>HCPCS coding changes.</td>
</tr>
<tr>
<td>05/15/03</td>
<td>Reviewed; limitation changed for allergenic extract.</td>
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<tr>
<td>05/15/04</td>
<td>Scheduled review; added “mediator release test” to list of non-covered services; formatting revisions.</td>
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<tr>
<td>05/15/05</td>
<td>Scheduled review; no change in coverage statement.</td>
</tr>
<tr>
<td>10/15/05</td>
<td>Revision consisting of adding information regarding SAGE food allergy test.</td>
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<tr>
<td>05/15/06</td>
<td>Scheduled review: added investigational statement for sublingual immunotherapy for allergies and added additional tests and immunotherapies for idiopathic environmental illness; updated references.</td>
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<tr>
<td>09/15/06</td>
<td>Revision consisting of adding 83516, 83518, 83519, 83520, and 86005 to the list of allergy tests.</td>
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<tr>
<td>01/01/07</td>
<td>Annual HCPCS coding update (deleted 95078.)</td>
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<tr>
<td>05/15/07</td>
<td>Scheduled review; reformatted guideline; no change in coverage statement.</td>
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<tr>
<td>01/01/08</td>
<td>Annual HCPCS coding update: descriptor revisions for codes 95004, 95024, and 95027.</td>
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<td>07/15/08</td>
<td>Scheduled review; no change in position statement; updated references.</td>
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<tr>
<td>01/01/09</td>
<td>Annual HCPCS coding update: revised descriptors for 95010 and 95015.</td>
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<tr>
<td>01/09/09</td>
<td>Revisions consisting of addition of criteria regarding IgG food allergy testing; reference added.</td>
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<tr>
<td>11/15/09</td>
<td>Scheduled review; no position statement changes; medical society information added regarding mixing of allergen extracts; reimbursement limitations revised; definitions added; references updated.</td>
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<tr>
<td>01/01/10</td>
<td>Annual HCPCS coding update: revised descriptors for 83516, 83518, 83519, and 83520.</td>
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<tr>
<td>04/15/10</td>
<td>Revision to Billing/Coding and Reimbursement sections regarding 83516, 83518, and 83519.</td>
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<tr>
<td>12/15/10</td>
<td>Scheduled review; Position Statement unchanged; added information regarding LEAP program; coding section revised; related ICD-10 codes added; references updated; formatting changes.</td>
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<tr>
<td>04/15/11</td>
<td>Revision to Reimbursement section of the guideline regarding allergen extracts.</td>
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<tr>
<td>07/15/11</td>
<td>Revision; formatting changes.</td>
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<tr>
<td>Date</td>
<td>Revision Notes</td>
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<tr>
<td>10/01/11</td>
<td>Revision to Reimbursement section.</td>
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<tr>
<td>12/15/11</td>
<td>Revisions to Billing/Coding and Reimbursement sections.</td>
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<tr>
<td>03/15/12</td>
<td>Revision; Reimbursement section updated.</td>
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<tr>
<td>11/15/12</td>
<td>Annual review; position statement reformatted, references updated, formatting changes.</td>
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<tr>
<td>01/01/13</td>
<td>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.</td>
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<tr>
<td>11/15/13</td>
<td>Annual review; position statements unchanged; Program Exceptions section updated; references updated.</td>
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<tr>
<td>11/15/14</td>
<td>Annual review; position statement regarding sublingual immunotherapy revised; references updated; formatting changes.</td>
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<tr>
<td>06/15/16</td>
<td>Added CPT code 86001.</td>
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<tr>
<td>08/15/17</td>
<td>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.</td>
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<tr>
<td>11/10/17</td>
<td>Revision: Added note regarding coverage of sublingual immunotherapy.</td>
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<tr>
<td>01/01/18</td>
<td>Annual CPT/HCPCS coding update: added 86008; revised 86003, 86005.</td>
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<tr>
<td>03/15/18</td>
<td>Revision: added criteria for aspirin desensitization; revised Reimbursement Information section; updated references.</td>
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<tr>
<td>08/15/18</td>
<td>Unscheduled review. Maintained position statement and updated references.</td>
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