EFFECTIVE DATE: 07|01|2026
POLICY LAST REVIEWED: 03|18|2026

OVERVIEW

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any organ system of the body. The reactions may be acute, subacute, or chronic, immediate, or delayed and may be caused by numerous offending agents, e.g., pollen, molds, dust, mites, animal dander, stinging insect venom, food(s), and double-blind food challenge tests. Diagnosing allergies often involves testing serum and skin. Other diagnostic procedures have been developed to elicit and assess hypersensitivity reactions including but not limited to intradermal, patch and ingestion challenge tests.

In vivo methodologies, which determine the presence of specific IgE by administering an IgE-specific allergen into, on or near the individual and monitoring the individual's physiologic response(s) which may include skin allergy testing (e.g., skin prick testing, skin scratch testing, intradermal testing, skin patch testing, and skin endpoint titration), and food challenges. In vitro allergy tests determines the presence of specific IgE or elevated total IgE by analyzing the individual's serum which may include ELISA and RAST testing. Skin prick testing and in vitro analyses of IgE are the most commonly performed allergy tests. The Antigen Leukocyte Antibody Test (ALCAT) is intended to identify foods and other environmental agents for which an individual may be intolerant. It is not intended to diagnose food allergies. The leukocyte histamine release test (LHRT) is a measurement of the amount of histamine released in-vitro to test for IgE mediated food allergies.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

<u>In Vitro (blood serum analysis) Allergy Testing</u>

Medicare Advantage Plans and Commercial Products

The following tests are covered when filed with a covered diagnosis (see Coding Section). All other indications are not covered/not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each (CPT code 86003)
- Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each (CPT code 86008)

Medicare Advantage Plans

The following tests are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes:

- ELISA/Act (Enzyme-linked Immunosorbent Assay/Advanced Cell Test) qualitative antibody testing
- LMRA (Lymphocyte Mitogen Response Assays) by ELISA/Act
- Leukocyte Histamine Release Test (LHRT)
- IgG ELISA, indirect method
- Qualitative multi-allergen screen

The Antigen Leukocyte Antibody Test (ALCAT) is not covered when performed to establish a diagnosis of food allergy, using the diagnosis codes listed in the Coding Section, as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
The following tests are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- ELISA/Act (Enzyme-linked Immunosorbent Assay/Advanced Cell Test) qualitative antibody testing
- LMRA (Lymphocyte Mitogen Response Assays) by ELISA/Act
- Leukocyte Histamine Release Test (LHRT)
- IgG ELISA, indirect method
- Qualitative multi-allergen screen

The Antigen Leukocyte Antibody Test (ALCAT) is not medically necessary when performed to establish a diagnosis of food allergy, using the diagnosis codes listed in the Coding Section, as the evidence is insufficient to determine the effects of the technology on health outcomes.

In Vivo (skin tests) Allergy Testing
Medicare Advantage Plans and Commercial Products
Intradermal and scratch allergy testing is medically necessary when the number of tests are chosen based on the patient's clinical presentation and clinician's judgement, and when the chosen tests are specific to the patients' history and physical examination findings.

ALL ALLERGY TESTING – IN VIVO AND IN VITRO
Medicare Advantage Plans and Commercial Products

The following applies to all allergy testing.

When allergy testing is covered:

- The number and type of antigens used for testing must be chosen judiciously given the patient's presentation and the tester's clinical judgement.
- The number of tests performed must be related to the history, physical findings and clinical judgement specific to each individual patient.

It is not expected that all patients would receive the same series or number of tests.

Retesting with the same antigens should rarely be necessary within a three-year period. Routine repetition of skin tests is not indicated (i.e., annually).

In general, allergy testing is not performed on the same day as allergy immunotherapy in standard medical practice. Allergy testing is performed prior to immunotherapy to determine the offending allergens. CPT codes for allergy testing and immunotherapy are generally not reported on the same date of service unless the physician provides allergy immunotherapy and testing for additional allergens on the same day. Physicians shall not report allergy testing CPT codes for allergen potency (safety) testing prior to administration of immunotherapy. Confirmation of the appropriate potency of an allergen vial for immunotherapy is an inherent component of immunotherapy. Additionally, allergy testing is an integral component of rapid desensitization kits (CPT code 95180) and is not separately reportable.

Some allergy testing CPT codes (e.g., 95004, 95017- 95052) are reported based on the number of individual tests performed. Positive or negative controls may not be included in the number of tests reported. For example, if percutaneous testing (CPT code 95018) with penicillin allergens administering 6 allergens plus a positive and negative control is performed, only 6 tests may be reported for CPT code 95018.

Medical Necessity Guidance is criteria used to establish medical necessity for testing and must be based on patient-specific elements identified during the clinical assessment, and documented by the clinician in the patient's medical record and minimally include the following elements:

- Patient history, physical examination and previous laboratory findings;
- Current treatment plan;
- Prescribed medication(s)
- Risk assessment plan

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COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Allergy is a form of exaggerated sensitivity or hypersensitivity to a substance that is either inhaled, ingested, injected, or comes in contact with the skin or eye. 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. Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any part of the body. The reactions may be acute, subacute, or chronic, immediate or delayed, and may be caused by a variety of offending agents; pollen, molds, mites, dust, feathers, animal fur or dander, venoms, foods, drugs, etc.

Allergy testing is performed to determine a patient's immunologic sensitivity or reaction to particular allergens for the purpose of identifying the cause of the allergic state, and is based on findings during a complete medical and immunologic history and appropriate physical exam.

Allergy testing can be broadly subdivided into two methodologies:

1. **In vivo testing** (skin tests): this testing correlates the performance and evaluation of selective cutaneous and mucous membrane tests with the patient's history, physician examination, and other observations. Examples of in vivo testing include:
    a. **Percutaneous Testing** (scratch, puncture, prick) and is used to evaluate immunoglobulin E (IgE) mediated hypersensitivity. Percutaneous tests require medical supervision, since there is a small but significant risk of anaphylaxis. Overall, skin testing is quick, safe, and cost effective. It remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected to inhalants, foods, hymenoptera (stinging insects) and specific drugs (penicillins, macromolecular agents, enzymes, and egg-containing vaccines). Skin testing is unreliable with other drugs. It remains the test of choice in most clinical situations where immediate hypersensitivity reactions are suspected.
    b. **Intracutaneous/Intradermal Tests** are usually performed when increased sensitivity is the main goal such as when percutaneous tests are negative and there is a strong suspicion of allergen sensitivity. Intradermal tests are injections of small amounts of antigen into the superficial layers of the skin. The usual testing program may include 2 concentrations of an extract: a weaker concentration and a stronger concentration. It would not be expected that 3 or more concentrations of one extract would be medically necessary. Medicare covers intradermal (intracutaneous) testing when IgE-mediated reactions occur to any of the following: Inhalants, hymenoptera (stinging insects), specific drugs (penicillins and macromolecular agents) or vaccines.
    c. **Patch Testing** is the gold standard method of identifying the cause of allergic contact dermatitis. This testing is indicated to evaluate a nonspecific dermatitis, pruritus, to differentiate allergic contact dermatitis (ACD) and irritant contact dermatitis (ICD) and determine the causative antigen. It is a diagnostic test reserved for patients with skin eruptions for which a contact allergy source is likely.
2. **In vitro testing** (blood serum analysis): immediate hypersensitivity testing by measurement of allergen-specific serum IgE in the blood serum. They are useful when testing for inhalant allergens (pollens,

molds, dust mites, animal danders), foods, insect stings, and other allergens such as drugs or latex, when direct skin testing is impossible due to extensive dermatitis, marked dermatographism, or in children younger than four years of age.

Environmental illness refers to a physiologic reaction that is triggered by an exogenous agent, which can be ingested, inhaled, or exposed through direct contact with skin. The physiologic reaction can be an immunologic response or a nonimmunologic response. An adverse physiologic reaction to exogenous antigens has been proposed to play a causative role in a wide variety of illnesses, including allergies, eczema, chronic fatigue, migraine headache, and gastrointestinal (GI) tract disorders such as irritable bowel syndrome.

Food allergy is the most well-defined type of environmental illness and is estimated to affect 8% of children. In most cases, true food allergy is characterized by a classic immunologic response, i.e., an immunoglobulin E-mediated reaction in response to a specific protein allergen. Reactions can range from mild symptoms to life-threatening anaphylaxis. Current guidelines for the diagnosis and management of food allergies have been developed by National Institute of Allergy and Infectious Disease (NIAID).

Food intolerance is a broader term that overlaps with food allergy but is less well-defined. Food intolerance refers to physiologic reactions that are triggered by a particular food, but which are not immune-mediated. It is hypothesized that physiologic reactions to food may manifest as a range of nonspecific symptoms, such as GI complaints, headache, fatigue, and musculoskeletal complaints and that these symptoms may become chronic with repeated exposure. An example of food intolerance, distinguished from a true food allergy, is lactose intolerance, in which dairy products incite a nonimmunologic reaction that can lead to a constellation of GI symptoms.

Treatment

Treatment of environmental illness primarily involves avoidance of the inciting agent. Acute allergic reactions are treated in the same way as other types of allergies with antihistamines, steroids, and supportive measures. In cases of severe allergy where an agent cannot be definitively avoided, patients can carry and self-administer auto-injectable epinephrine when needed. Prophylactic antihistamines can also be used to prevent or lessen reactions. Allergy immunotherapy may be appropriate for selected allergens.

For patients with food intolerance that is not allergy based, identification of the inciting agent(s) can be difficult because the symptoms are chronic. Use of an elimination diet is considered the best way to identify intolerant agents. In an elimination diet, one specific food or food group is eliminated from the diet for a specified period, and symptoms are observed. Following the elimination period, a rechallenge can be performed to ascertain whether symptoms return. Elimination diets often need to be done sequentially with a large number of items, so the process can be lengthy and cumbersome.

The umbrella term "food hypersensitivity for food sensitivities" can be used to describe any "adverse reaction to food." The term "food allergy" refers to the subgroup of food-triggered reactions in which immunologic mechanisms have been implicated, whether IgE-mediated, non-IgE mediated, or involving a combination of IgE and non-IgE mediated etiologies. All other reactions to food that were in the past sometimes referred to as "food intolerance" or "food sensitivities" constitute non-allergic food hypersensitivity reactions and are not considered food allergies.

Antigen Leukocyte Antibody Test

The antigen leukocyte antibody test (ALCAT) is intended to identify foods and other environmental agents for which an individual may have intolerance. It is not intended to diagnose food allergy. The test is based on the theory that a substantial increase in leukocyte size and number is characteristic of an intolerant response. Identifying the specific inciting agent facilitates avoidance of that agent, which may lead to a reduction in symptoms. In this regard, ALCAT testing has been used as a tool for developing an elimination diet that is targeted to the most likely offending agents.

The test is performed by taking a sample of blood, which is first treated to remove the red blood cells and tested to determine the baseline number and size of leukocytes and platelets. Measurement of size and count of cells is performed by the Coulter technique, which is a standard technique in clinical hematology. Next, a small quantity of blood is incubated with multiple agents. Following exposures, change in the number and size of cells is determined for each exposure. A 10% increase in the size of leukocytes is considered characteristic of a response to an intolerant agent.

The ALCAT website (Cell Sciences Systems) lists 11 separate panels consisting of various combinations of foods, herbs, food additives/coloring, and environmental chemicals. The total number of agents tested in these panels ranges from 81 to 370.

For individuals who have a suspected intolerance of environmental agents or food who receive the ALCAT, the evidence includes a randomized controlled trial and case series. Relevant outcomes are morbid events and medication use. There is a lack of published research on the diagnostic accuracy of ALCAT; therefore, it is not possible to determine the sensitivity, specificity, and/or predictive value of the test compared with alternatives. A few low-quality studies have reported improvements in outcomes following the use of ALCAT, but it is not possible to determine whether these changes occurred as a result of the test itself, bias, variation in the natural history of the condition, and/or the placebo effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Leukocyte Histamine Release Test

The leukocyte histamine release test (LHRT) is designed to provide an in vitro correlate to an in vivo allergic response (i.e., skin prick testing). An allergen is added to the peripheral blood leukocytes of the individual being tested and the in vitro release of histamine from basophils in response to exposure to the allergen is measured. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies. In contrast, the RAST test (radioallergosorbent test) attempts to correlate the presence of allergy to serum levels of antigen-specific IgE as an index of allergic reactivity. Initially, measurements of histamine release required isolation of leukocytes from whole blood followed by the isolation of the released histamine; the laboratory techniques were difficult and time-consuming and thus LHRT was primarily used as a research tool only. Recently, a special type of glass fiber has been developed that binds histamine with high affinity and selectivity. These glass fibers can be used as a "solid phase" to absorb the histamine that is released directly into the blood. The recent commercial availability of simplified and automated methods of laboratory analysis (i.e., both ELISA and radioimmunoassays) have renewed interest in the clinical applications of LHRT in the evaluation of food, inhalant, and drug allergies. Overall, studies are not sufficient to permit conclusions on the diagnostic accuracy of LHRT, and therefore LHRT is considered not medically necessary.

LMRA (Lymphocyte Mitogen Response Assays) by ELISA/Act

LMRA (Lymphocyte Mitogen Response Assays) by ELISA/Act measure the ability of lymphocytes to respond in vitro to an activation stimulus. This method requires the isolation of peripheral blood mononuclear cells, which are then put in tissue culture with a foreign antigen of interest. Subsequent measurement of the number of dividing cells indicates immune stimulation. There is a lack of evidence to support the efficacy of LMRA testing for the diagnosis and treatment of allergies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcomes.

Serum IgE Testing - Radioallergosorbent Test (RAST) or Enzyme-linked Immunosorbent Assay (ELISA)

Radioallergosorbent test (RAST), fluoroallergosorbent test (FAST), and multiple antigen simultaneous tests are in vitro techniques for determining whether a patient's serum contains IgE antibodies against specific allergens of clinical importance. As with any allergy testing, the need for such tests is based on the findings during a complete history and physical examination of the patient.

The multiple antigen simultaneous testing technique is similar to the RAST/FAST techniques in that it depends upon the existence of allergic antibodies in the blood of the patient being tested. With the multiple antigen simultaneous test system, several antigens may be used to test for specific IgE simultaneously.

ELISA (enzyme-linked immunosorbent assay) is another in vitro method of allergy testing for specific IgE antibodies against allergens. This method is also a variation of RAST. ELISA/Act qualitative antibody testing is used to determine the in vitro reaction to various foods and relies on lymphocyte blastogenesis in response to certain food antigens. The ELISA/Act qualitative antibody testing is not approved by the FDA (Food and Drug Administration) and is not established as a useful test in clinical practice.

IgG and IgG subclass antibody test for food allergy do not have clinical relevance, are not validated, lack sufficient quality control and should not be performed.

CODING

In Vitro Allergy Testing

Medicare Advantage Plans

The following CPT codes are considered medically necessary when filed with the diagnosis codes in the attachment linked below:

86003 Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
86008 Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each

ICD-10 Codes for 86003 and 86008 for Medicare Advantage Plans

Note: The list of ICD-10 diagnosis codes for 86003 and 86008 for Medicare Advantage Plans differs from the ICD-10 diagnosis codes for 86003 and 86008 for Commercial Products.

Commercial Products

The following CPT codes are considered medically necessary when filed with the diagnosis codes in the attachment linked below:

86003 Allergen specific IgE; quantitative or semiquantitative, crude allergen extract, each
86008 Allergen specific IgE; quantitative or semiquantitative, recombinant or purified component, each

ICD-10 Codes for 86003 and 86008 for Commercial Products

Note: The list of ICD-10 diagnosis codes for 86003 and 86008 for Commercial Products differs from the ICD-10 diagnosis codes for 86003 and 86008 for Medicare Advantage Plans.

Medicare Advantage Plans and Commercial Products

The following CPT codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

86001 Allergen specific IgG quantitative or semiquantitative, each allergen
86005 Allergen specific IgE; qualitative, multiallergen screen (eg, disk, sponge, card)
86343 Leukocyte histamine release test (LHR)

Note: the above codes can be used for

- IgG ELISA, indirect method (LCD 86001)
- Qualitative multi-allergen screen (LCD 86005)
- Leukocyte Histamine Release Test (LHRT) (86343)

The following CPT code is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when filed with the diagnosis codes listed below:

83516 Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method

Note: the above code can be used for:

- Antigen Leukocyte Antibody Test (ALCAT)

*NOTE: There are various sizes of ALCAT panels and they are likely reported with multiple units of CPT code 83516.

ICD-10 Diagnosis Codes Not Covered/Not Medically Necessary with CPT 83516
K52.21-K52.29
Z91.010-Z91.018
Z91.02

The following Unlisted CPT code can be used for any test identified in this policy that does not have a specific CPT code.
86849 Unlisted immunology procedure

In Vivo Allergy Testing
Medicare Advantage Plans and Commercial Products
The following CPT codes are covered, ***at the limits found in the grid below***, when performed according to the guidelines in the policy statement. Note: For intradermal allergy testing, CPT 95024 and CPT 95028 are subject to a combined plan specific annual maximum of 40 total units per calendar year, regardless of the distribution between immediate and delayed intradermal testing. This combined limit represents a utilization management policy and does not establish independent per code maximums.

*Positive or negative control testing may not be included in the number of units reported.

CPT Code and Explanation	Type of Test	Annual Maximum Allowed Units	Units Explanation
95004 – A physician or other qualified health care provider scratches, punctures, or pricks the skin to introduce specific allergy extracts to determine a patient's allergies. The immediate skin reaction is documented. This code includes test interpretation and provider report.	Scratch/Percutaneous	80	A total of 80 scratch, puncture, or prick allergy tests are eligible for reimbursement per calendar year.
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.	Scratch/percutaneous and Intradermal	27	A total of 27 tests filed under 95017 are eligible for reimbursement per calendar year.
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.	Scratch/percutaneous and Intradermal	19	A total of 19 tests filed under 95018 are eligible for reimbursement per calendar year.
95027 - A physician or other qualified health care provider uses intracutaneous tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, to determine a patient's specific allergies. The	Intradermal/ intracutaneous	90	A total of 90 tests filed under 95027 are eligible for reimbursement per calendar year.

number of tests must be specified. This code includes test interpretation and provider report.			
95024 - A physician or other qualified health care provider injects suspected allergenic substances into the skin to determine the patient's specific allergies. The immediate skin reaction is documented. This code includes test interpretation and provider report.	Intradermal/ intracutaneous	40	A total of 40 intracutaneous allergy tests are eligible for reimbursement per calendar year. 40 units is the maximum allowed for codes 95024 and 95028. (Example: 40 units for 95024, or 20 units for 95024 **AND** 20 units for 95028). **NOTE:** Intracutaneous allergy tests should only follow negative scratch, puncture or prick tests.
95028 - Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests.	Intradermal/ intracutaneous	40	A total of 40 intracutaneous allergy tests are eligible for reimbursement per calendar year. 40 units is the maximum allowed for codes 95024 and 95028. (Example: 40 units for 95024, or 20 units for 95024 **AND** 20 units for 95028). **NOTE:** Intracutaneous allergy tests should only follow negative scratch, puncture or prick tests.
95052 - Photo patch test(s) (specify number of tests).	Photo	36	A total of 36 photo tests are eligible for reimbursement per calendar year.

RELATED POLICIES
Not applicable

PUBLISHED
Provider Update, May 2026

Provider Update, September/December 2025
Provider Update, February/December 2024
Provider Update, January 2023
Provider Update, February/August 2021

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