

Allergy Testing

CPT: 86003, 86008

CMS Policy for Indiana

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive
ICD Codes are listed
on subsequent page(s)
of this document.

Coverage Indications, Limitations, and/or Medical Necessity

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. It is based on findings during a complete medical and immunologic history, and appropriate physical exam obtained by face-to-face contact with the patient.

Indications

Allergy skin testing is a clinical procedure that is used to evaluate an immunologic response to allergenic material. It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number and type of antigens used for testing must be chosen judiciously given the patient's presentation, history, physical findings, and clinical judgment.

To be covered by Medicare, the antigens must meet all of the following criteria:

1. Skin testing must be performed based on a complete history and physical exam,
2. Proven efficacy as demonstrated through scientifically valid peer reviewed published medical studies, and
3. Exist in the patient's environment with a reasonable probability of exposure

Allergy testing can be broadly subdivided into two methodologies:

A. 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.

1. **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.

Percutaneous testing is the usual preferred method for allergy testing. Medicare covers percutaneous (scratch, prick or puncture) testing when IgE-mediated reactions occur with **any** of the following:

- a) Inhalants.
- b) Foods. (Patients present with signs and symptoms such as urticarial, angioedema, eosinophilic esophagitis, or anaphylaxis after ingestion of specific foods. Testing for food allergies in patients who present with wheezing is occasionally required.)
- c) Hymenoptera (stinging insects).
- d) Specific drugs (penicillins, macromolecular agents, enzymes, and egg-containing vaccines). Skin testing is unreliable with other drugs.

2. **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:

- a) Inhalants.
- b) Hymenoptera (stinging insects).
- c) Specific drugs (penicillins and macromolecular agents).
- d) Vaccines.

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3. **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.

The patch test procedure can induce an eczematous reaction in miniature by applying suspect allergens to normal skin, allowing the physician to determine a specific patient allergy. Patch tests are applied to the skin on the patient's back and left in place for 48 hours. The test is interpreted after 48 hours, and typically once again at 72 or 96 hours, and the reactions are systematically scored and recorded. The patient is then informed and educated regarding specific allergies and avoidance of exposure. Avoidance of the identified allergen(s) is critical to patient improvement and resolution of the dermatitis.

Allergy patch testing is a covered procedure only when used to diagnose allergic contact dermatitis after the following exposures: dermatitis due to detergents, oils and greases, solvents, drugs and medicines in contact with skin, other chemical products, food in contact with skin, plants (except food), cosmetics, metals, rubber additives, other and unspecified. Patch tests may also be used and may be helpful when a distribution and persistence of dermatitis suggests a possible contact allergy, but the exact etiology of the dermatitis is unknown. These allergens are part of a useful, but limited series of 36 allergens. While this series of 36 allergens represents some of the most common contact allergies, there are a significant number of patients who suffer intractable contact dermatitis for which the 36 allergens are inadequate to diagnose their problem. A supplemental series of allergens in this case can enhance accurate diagnosis, patient education, and treatment. This supplemental series is particularly critical in the diagnosis of occupationally induced dermatitis. If another supplemental series of allergens are clinically indicated for an accurate diagnosis, the documentation must support the medically reasonable and necessary use of the additional allergens.

The clinician should recognize that contact sensitization to metals or bone cement that is used in orthopedic, cardiac, dental, and gynecological implants has been associated with both dermatitis and noncutaneous complications. These complications may include localized pain, swelling, erythema, warmth, implant loosening, decreased range of motion, stent stenosis, and pericardial effusions in the case of cardiac implants. Patch testing to implant or device components has been recommended to help determine the etiology of the adverse reaction.

4. **Photo Patch Testing** uses two patches, with one of them being irradiated with ultraviolet light half way through the occlusive period. It is indicated to evaluate unique allergies resulting from light exposure. Some chemicals or medications produce an allergic reaction only when exposed to light (usually ultraviolet type A, UVA). Patients who are over-sensitive to light and those with a rash that appears on parts of the body normally exposed to light but that does not appear in areas shielded from the light should have a photo-patch test.

5. **Photo Tests** is skin irradiation with a specific range of ultraviolet light. Photo tests are performed for the evaluation of photosensitivity disorders.

6. **Skin Endpoint Titration (SET) Testing or Intradermal Dilutional Testing (IDT)** analyzes the highest dilution of a substance that produces a reaction, and may be used to determine the starting dose(s) of allergen immunotherapy.

7. **Delayed Hypersensitivity Skin Testing** has been commonly used in three ways: anergy testing, testing for infection with intracellular pathogens, and testing for sensitivity to contact allergens. Accurate testing for contact allergy requires careful attention to technique, and limitation of testing to the specific allergens known to be associated with a contact reaction.

8. **Ophthalmic Mucous Membrane Tests and Direct Nasal Mucous Membrane Tests** are rarely indicated. They are allowed when skin testing cannot test allergens. Ophthalmic mucous membrane tests and direct nasal mucous membrane tests are approved if levels of allergic mediators (such as histamine and tryptase) are measured and a placebo control is performed. This is usually performed in allergy research laboratories. It is also approved in the office setting if the physician is there to observe objective measurement of reactions which might include redness of the eyes, tearing and sneezing.

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9. Inhalation Bronchial Challenge Testing involves the inhalation of agents that can trigger respiratory responses and are often used to evaluate new allergens and/or substantiate the role of allergens in patients with significant symptoms. Results of these tests are ordinarily evaluated by objective measures of pulmonary function and occasionally by characterization of bronchoalveolar lavage samples.

- a) Inhalation bronchial challenge tests should be performed as dose-response assays where in provocation concentration thresholds can be determined on the basis of allergen concentration required to cause a significant decrease in measured pulmonary function.
- b) Inhalation bronchial challenge tests with occupational allergens need to be carefully controlled with respect to dose and duration of exposure. When industrial small molecular weight agents are assessed, tests should be performed under conditions of continuous monitoring of the specific chemical being assessed so as not to exceed the threshold limit level permitted in the workplace.

10. Ingestion (Oral) Challenge Test involves the administration of sequentially or incrementally larger doses of the test item. The test items may include food or antibiotics. The service is allowed once per patient encounter, regardless of the number of items tested, and includes evaluation of the patient's response to the test items.

Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis if it is reasonable and necessary for the individual patient. (CMS Pub. 100-03 Medicare National Coverage Determination (NCD) Manual, Chapter 1- Coverage Determinations, Part 2 Section 110.12- Challenge Ingestion Food Testing).

Challenge ingestion food testing is covered for the following indications:

- Food allergy, dermatitis
- Anaphylactic shock due to adverse food reaction
- Allergy to medicinal agents
- Allergy to foods

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of section 1862(a) (1) of the Medicare law, and no program payment is made for this procedure when it is so used. (CMS Pub. 100-03 Medicare National Coverage Determination (NCD) Manual, Chapter 1 – Coverage Determinations, Part 2 Section 110.12- Challenge Ingestion Food Testing).

11. Intracutaneous testing, delayed reaction - more than 6 tests, may be covered but requires additional justification and case-by-case review for the number of tests performed and the medical necessity except when the skin test is used:

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4-week period. CMS Pub 100-03 Medicare National Coverage Determinations (NCD) Manual, Chapter 1 – Coverage Determinations, Part 4, Section 230.10 – Incontinence Control Devices.

12. Organ challenge test materials may be applied to the mucosae of the conjunctivae, nares, GI tract, or bronchi. Considerable experience with these methods is required for proper interpretation and analysis. All organ challenge tests should be preceded by a control test with diluent and, if possible, the procedure should be performed on a double blind or at least single-blind basis.

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B. 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.

In vitro testing is covered when skin testing is not possible or would be unreliable; or in vitro testing is medically reasonable and necessary as determined by the physician. When in vitro testing is ordered or performed, the medical record must clearly document the indication and why it is being used instead of skin testing.

It is not covered when done in addition to a skin test for the same antigen, except in the case of suspected latex sensitivity, hymenoptera, or nut/peanut sensitivity where both the skin test and the in-vitro test may be performed. The number of tests done, choice of antigens, frequency of repetition and other coverages issues are the same as skin testing.

Testing must be based on a careful history/physical examination which suggests IgE mediated disease. Total Serum IgE is not appropriate in most general allergy testing. Instead, individual IgE tests are performed against a specific antigen.

Special clinical situations in which specific IgE immunoassays are performed against a specific antigen may be appropriate in the following situations:

1. Patients with extensive dermatitis, severe dermatographism, ichthyosis or generalized eczema that will not make direct skin testing possible.
2. Patients needing continued use of H-1 blockers (antihistamines), or in the rare patient with persistent unexplained negative histamine control.
3. Patients who cannot be safely withdrawn from medications that interfere with skin testing, such as long-acting antihistamines, tricyclic antidepressants, beta-blockers, or medications that may put the patient at undue risk if they are discontinued long enough to perform skin tests.
4. Uncooperative patients with mental or physical impairments.
5. For evaluation of cross-reactivity between insect venoms (e.g., fire ant, bee, wasp, yellow jacket, hornet).
6. As adjunctive laboratory testing for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic disease.
7. To diagnose atopy in small children.
8. Patients at increased risk for anaphylactic response from skin testing based on clinical history (e.g., when an unusual allergen is not available as a licensed skin test extract), or who have a history of a previous systemic reaction to skin testing.
9. Patients in who skin testing were equivocal/inconclusive and in vitro testing is required as a confirmatory test.

Total IgE is reasonable and necessary for follow-up of Allergic Bronchopulmonary Aspergillosis (ABPA) and to diagnosis atopy in children.

Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include young children with negative skin tests, or older children and adults with negative skin tests in the face of persistent symptoms. Routine repetition of skin tests is not indicated (i.e., annually) and not covered.

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Limitations – The following tests are considered not medically reasonable and necessary:

1. **Ingestion (Oral) Challenge Food Testing** performed by the patient in the home, and not in the office setting, will not be covered.

2. **Provocative Testing** for which there is limited or no evidence of validity include the cytotoxic test, the provocation-neutralization procedure, electrodermal diagnosis, applied kinesiology, the "reaginic" pulse test, and chemical analysis of body tissues. Controlled studies for the cytotoxic and provocation-neutralization tests demonstrated that the results are not reproducible and do not correlate with clinical evidence of allergy. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. Similarly, the "reaginic" pulse test and chemical analysis of body tissues for various exogenous chemicals have not been substantiated as valid tests for allergy.

Provocative and neutralization testing and neutralization therapy (Rinkel test) of food allergies (sublingual, intracutaneous and subcutaneous) are excluded from Medicare coverage because available evidence does not show these tests and therapies are effective.

3. **IgG and IgG Subclass Antibody Tests** measure allergen-specific IgG and IgG subclasses by using immunoabsorption assays and IgG and IgG subclass antibody tests for food allergy/delayed food allergic symptoms or intolerance to specific foods. These tests are considered experimental and investigational since there is insufficient evidence in the published peer-reviewed scientific literature to support the diagnostic value of these tests.

4. **Antigens** for which no clinical efficacy is documented in peer reviewed literature include the following: newsprint, tobacco smoke and leaf, dandelion, orris root, phenol, alcohol, sugar, yeast, grain mill dust, soybean dust (except when the patient has a known exposure to soybean dust such as a food processing plant), honeysuckle, marigold, goldenrod, fiberglass, wool, green tea, or chalk.

5. **Radioallergosorbent test (RAST), fluoroallergosorbent test (FAST), and multiple antigen simultaneous test (MAST)** 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. These tests are not appropriate in most general allergy testing. Instead, individual IgE tests should be performed against a specific antigen.

6. **ELISA (enzyme-linked immunoabsorbent assay) test** is another in vitro method of allergy testing for specific IgE antibodies against allergens. It is used to determine in vitro reaction to various foods and relies on lymphocyte blastogenesis in response to certain food antigens.

7. **Quantitative multi-allergen screen** is a non-specific screen that does not identify a specific antigen. It does not have sufficient literature demonstrating clear cut clinical implication. It is a screening tool and therefore not covered by Medicare.

8. *Effective August 5, 1985, **cytotoxic leukocyte tests** for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective. (CMS Pub. 100-03 Medicare National Coverage Determination (NCD) Manual, Chapter 1- Coverage Determinations, Part 2 Section 110.13-Cytotoxic Food Tests).*

9. *Effective October 31, 1988, **sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy** for food allergies are excluded from Medicare coverage because available evidence does not show that these tests and therapies are effective. (CMS Pub 100-03 Medicare National Coverage Determinations Manual, Chapter 1- Coverage Determinations, Part 2, Section 110.11 – Food Allergy Testing and Treatment).*

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10. The following tests are considered **experimental and investigational for allergy testing** as these have not been proven to be effective or appropriate for the evaluation and/or management of IgE-mediated allergic reactions. This list is not all inclusive:

- A. Antigen leukocyte cellular antibody (ALCAT) automated food allergy testing
- B. Applied kinesiology or Nambudripad's allergy elimination test (NAET) (ie, muscle strength testing or measurement after allergen ingestion)
- C. Anti-Fc epsilon receptor antibodies testing
- D. Anti-IgE receptor antibody testing
- E. Blood, urine, or stool micro-nutrient assessments
- F. Candidiasis test
- G. Chemical analysis of body tissues (eg, hair)
- H. Chlorinated pesticides (serum)
- I. Chronic urticarial index testing
- J. Clifford materials reactivity testing
- K. Complement (total or components)
- L. Complement antigen testing
- M. C-reactive protein
- N. Cytokine and cytokine receptor assay
- O. Cytotoxic testing for environmental or clinical ecological allergy testing (Bryans Test, ACT)
- P. Electrodermal testing or electro-acupuncture
- Q. Electromagnetic sensitivity syndrome/disorder (allergy to electricity, electro-sensitivity, electrohypersensitivity, and hypersensitivity to electricity)
- R. Environmental cultures and chemicals
- S. Eosinophil cationic protein (ECP) test
- T. Food immune complex assay (FICA) or food allergenic extract immunotherapy
- U. General immune system assessments
- V. Immune complex assay
- W. Immunoglobulin G (IgG) testing for allergy
- X. Iridology
- Y. Leukocyte antibodies testing
- Z. Leukocyte histamine release test (LHRT)/basophil histamine release test
 - aa. Lymphocytes (B or T subsets)
 - ab. Lymphocyte function assay
 - ac. Mediator release test (MRT) or the LEAP program
 - ad. Metabolic assessments
 - ae. Multiple chemical sensitivity syndrome (aka, 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)
 - af. Prausnitz-Kustner or P-K testing - passive cutaneous transfer test
 - ag. Pulse response test
 - ah. Qualification of nutritional assessments
 - ai. Rebeck skin window test
 - aj. Secretory IgA (salvia)
 - ak. Sage Complement Antigen Test
 - al. Specific Immunoglobulin (IgG) (eg, by Radioallergosorbent (RAST) or Enzyme-linked immunosorbent assay (ELISA)
 - am. Sublingual provocative neutralization testing and treatment with hormones
 - an. Total serum IgG, immunoglobulin A (IgA) and immunoglobulin M (IgM)
 - ao. Venom blocking antibodies
 - ap. Volatile chemical panels (blood testing for chemicals)
 - aq. Live Cell Analysis
 - ar. Passive Transfer
 - as. Cytotoxic Food Testing

Routine allergy re-testing does not meet the definition of medically necessity according to the practice parameters and recommendations from the American College of Allergy, Asthma, and Immunology (ACAAI), the American Academy of Allergy, Asthma, and Immunology (AAAAI), and the Joint Council of Allergy, Asthma, and Immunology (JCAAI).

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Documentation Requirements

Adequate documentation is essential for high-quality patient care and to demonstrate the reasonableness and medical necessity of the testing. Documentation must support the criteria for coverage as described in the Coverage Indications, Limitations, and/or Medical Necessity section of this LCD. There should be a permanent record of the allergy test and its interpretation including the test methodology and either the measurement (in mm) of reaction size of both the wheal and erythema response or a standardized grading system for in vivo testing. If in vitro testing is used, instead of skin testing, the medical necessity must be documented. For the in vitro testing, the quantitative result(s) (in kIU/L) for specific IgE must be documented. All patient reaction(s) or complications should be recorded. The report should address or answer any specific clinical questions. If there are factors that prevent answering the clinical questions, this should be explained in the documentation. An official interpretation (final report) of the testing should be included in the patient's medical record. Retention of the allergy test(s) should be consistent both with clinical need and with relevant legal and local health care facility requirements.

The medical record must document the elements of the medical and immunologic history including but not limited to correlation of symptoms; occurrence of symptoms; exposure profile; documentation of allergic sensitization by accepted means and where attempts at avoidance have proven unsuccessful (or the impracticality of avoidance exists); and a copy of the sensitivity results; along with the physical examination. The history should support that attempts to narrow the area of investigation were taken so that the minimal number of necessary skin tests might deliver a diagnosis. Testing results need to justify the diagnosis and code on each claim form. The clinical condition that is claimed to justify this test must be clearly documented in the record. Note: A payable diagnosis alone does not support medical necessity of ANY service. The interpretation of the test results and how the results of the test will be used in the patient's plan of care for treatment and the management of the patient's medical condition (s) must be documented.

Claims submitted without such evidence will be denied as not medically necessary. When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

All documentation must be maintained in the patient's medical record and made available to Medicare upon request.

Utilization Guidelines

It is expected that these services would be performed as indicated by current medical literature and/or standards of practice. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

It would not be expected that all patients would receive the same tests or the same number of sensitivity tests. The number of tests performed must be judicious and related to the history, physical findings and clinical judgment specific to each individual patient. The selection of antigens should be individualized, based on the history and physical examination.

Retesting with the same antigen(s) should rarely be necessary within a three-year period. Exceptions include young children with negative skin tests or older children and adults with negative skin tests, but persistent symptoms suggestive of allergic disease where skin tests may be repeated one year later. Claims for retesting within a three-year period should be submitted with documentation of the medical necessity.

Testing done on separate days for different antigens is acceptable as long as the total number of tests done within any three-year period is not excessive.

In vitro testing is covered when medically reasonable and necessary as a substitute for skin testing; it is not usually necessary in addition to skin testing. If in vitro testing is inconclusive, and contraindications for skin testing have been resolved, then skin testing may be done and is covered. The medical record must document this rationale. In vitro IgE testing will be limited to 30 allergens/beneficiary over a 12-month period. If more tests are performed, medical records may be requested.

A maximum of 55 allergy patch tests for diagnose of allergic contact dermatitis per beneficiary per year is allowed without the submission of documentation with the claim to support medical necessity. Greater than 55 patch tests per patient per year may result in a request of medical records.

It would not be expected that more than forty (40) units be reported for intracutaneous (intradermal) testing per year for a patient. If more than 40 units are reported, medical records may be requested.

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There is a frequency associated with this test. Please refer to the Limitations or Utilization Guidelines section on previous page(s).

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare’s limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

**Note—Bolded diagnoses below have the highest utilization*

Code	Description
J30.1	Allergic rhinitis due to pollen
J30.89	Other allergic rhinitis
J45.40	Moderate persistent asthma, uncomplicated
R05	Cough
R06.02	Shortness of breath
T78.40XA	Allergy, unspecified, initial encounter

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Disclaimer:

This diagnosis code reference guide is provided as an aid to physicians and office staff in determining when an ABN (Advance Beneficiary Notice) is necessary. Diagnosis codes must be applicable to the patient’s symptoms or conditions and must be consistent with documentation in the patient’s medical record. Quest Diagnostics does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff. The CPT codes provided are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

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