J5 – Allergy Testing

CPT: 86001,86003,86008

CMS Policy

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

Overview:

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) 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, esosinophilic 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.

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.**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 1 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.

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.

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 2 patches, with 1 of them being irradiated with ultraviolet light halfway 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.

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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 3 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.
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 covered for the following indications:
• Food allergy, dermatitis
• Anaphylactic shock due to adverse food reaction
• Allergy to medicinal agents
• Allergy to foods
Challenge Ingestion is not payable when used to diagnosis rheumatoid arthritis, depression, or respiratory disorders. (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:
For collagen implant therapy. Refer to: 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 4-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 medicated 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. Adjunctive laboratory testing for disease activity of allergic bronchopulmonary aspergillosis and certain parasitic disease.
7. 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.

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Retesting with the same antigen(s) should rarely be necessary within a 3-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.

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 immunoaorbent 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 is does not have sufficient literature demonstrating clear cut clinical implication. It is a screening tool and therefore not covered by Medicare.

8. Cytotoxic leukocyte tests are excluded. (CMS Pub. 100-03 *Medicare National Coverage Determination (NCD) Manual,* Chapter 1- Coverage Determinations, Part 2 Section 110.13-Cytotoxic Food Tests).

9. Sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded. (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 (i.e., 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 (e.g., 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 (a.k.a., idiopathic environmental intolerance (IEI), clinical ecological illness, clinical ecology, environmental illness, chemical AIDS, environmental/chemical hypersensitivity disease, total allergy syndrome, cerebral allergy, 20th century disease)
af. Prausnitz-Kustner or P-K testing - passive cutaneous transfer test
ag. Pulse response test
ah. Qualification of nutritional assessments
ai. Rebuck skin window test
aj. Secretory IgA (salvia)
ak. Sage Complement Antigen Test
al. Specific Immunoglobulin (IgG) (e.g., 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).

J5 – Allergy Testing

CPT: 86003,86008

CMS Policy

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.

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.**

Code	Description
J30.1	Allergic rhinitis due to pollen
J30.2	Other seasonal allergic rhinitis
J30.5	Allergic rhinitis due to food
J30.89	Other allergic rhinitis
J31.0	Chronic rhinitis
J45.40	Moderate persistent asthma, uncomplicated
K29.60	Other gastritis without bleeding
L20.89	Other atopic dermatitis
L27.2	Dermatitis due to ingested food
L29.9	Pruritus, unspecified
L50.1	Idiopathic urticaria
R05.3	Chronic cough
R06.02	Shortness of breath
R09.81	Nasal congestion
R21	Rash and other nonspecific skin eruption
T78.1XXA	Oth adverse food reactions, not elsewhere classified, init
T78.40XA	Allergy, unspecified, initial encounter
Z88.8	Allergy status to other drug/meds/biol subst
Z91.011	Allergy to milk products
Z91.018	Allergy to other foods

Visit **QuestDiagnostics.com/MLCP** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

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