MP 2.04.500
Diagnostic Tests for Allergic and Immune Deficiency Diseases of Uncertain Efficacy

Last Review: 04/30/2018
Effective Date: 04/30/2018
Section: Medicine

Related Policies
9.01.502 Experimental / Investigational Services

DISCLAIMER
Our medical policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

POLICY
The following allergy tests are considered investigational, because they have not been shown to improve net health outcomes:

1. Antigen leukocyte cellular antibody (ALCAT) automated food test
2. Applied kinesiology allergy test
3. Conjunctival challenge test (ophthalmic mucous membrane test)
4. Cytotoxic food tests
5. Electrodernal testing (also known as electro-acupuncture)
6. Hair analysis
7. IgG/IgG4 allergen specific antibody test and food tests
8. Iridology
9. Leukocyte histamine release test (LHRT)
10. Nasal challenge test
11. Passive transfer of P-X (Prausnitz-Küstner) test (now considered obsolete-and replaced by Radioallergosorbent tests)
12. Provocation-neutralization food or food additive allergy test
13. Rebuck skin window test (no longer in use)

POLICY GUIDELINES
The following allergy tests are considered clinically useful for allergy confirmation by the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) in the diagnosis and management of the allergic patient:

- Bronchial challenge test
- Double-blind food challenge test
- Intradermal skin testing
- Patch test
- Percutaneous skin tests such as the scratch, prick, or puncture tests
Unproven and Inappropriate Diagnostic Tests for Allergic and Immune Deficiency Diseases

- Photo patch test
- Specific IgE in vitro tests such as Radioallergosorbent Test (RAST), Multiple Radioallergosorbent Tests (MAST), Fluorescent Allergosorbent Test (FAST), Enzyme-linked Immunosorbent Assay (ELISA), and the ImmunoCAP IgE test
- Total serum IgE concentration

This policy addresses only allergy tests which are unproven or inappropriate based upon the scientific literature.

**BENEFIT APPLICATION**

**BLUE CARD/NATIONAL ACCOUNT ISSUES**

State or federal mandates (e.g., Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

**BACKGROUND**

**ALLERGY TESTS OF UNCERTAIN EFFICACY**

This policy addresses only allergy tests of uncertain efficacy and those used primarily in research settings. Tests which may be considered useful in the clinical setting, as noted above, are not addressed in this policy.

**Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Test**

The ALCAT automated food test measures whole blood leukocytes by a proprietary process that identifies allergens which cause an increase in leukocyte activity. An electronic counter measures the change in number and size of white blood cells which have been incubated with purified food or mold extracts. A histogram is produced based on cell count and cell size. Individually processed test samples are compared with a 'Master Control' graph. Scores are generated by relating these effective volumetric changes in white blood cells to the control curve.

**Applied Kinesiology (Or Muscle Strength Test)**

Muscle strength in the extremities is measured before and after a person is exposed to an allergen. Strength in the opposing arm is measured as a person holds a container of allergen extract in the opposite hand or ingests an allergen. A decrease in strength indicates the presence of disease and various nutritional supplements may be recommended.

**Cytotoxic Food Tests**

This test involves the response of especially collected white blood cells to the presence of food extracts to which the patient is allergic. A technician observes the unstained cells for changes in shape and appearance of the leukocytes. Swelling, vacuolation, crenation, or other cytotoxic changes in cell morphology are taken as evidence of allergy to the food.

**Electrodermal Testing (Also Known As Electro-Acupuncture)**

This test measures changes in skin resistance while a person is exposed to an allergen; either food or inhalant using an instrument that measures the electrical resistance of the skin. A drop in the resistance of the skin is believed to indicate the presence of allergy.

**Hair Analysis**
Hair is analyzed for the presence (or lack) of various minerals and toxins. Findings are correlated to nutritional deficiencies or disease. Recommendations for diet and supplements are provided based on the analysis.

**Iridology**

According to the AAAI, iridology attempts to relate the anatomical features in the iris to various systemic diseases.

**Igg/Igg4 Antibody Test And Food Specific Igg/Igg4 Tests**

There are four subclasses of immunoglobulin G. Selective deficiencies in one or more of the four IgG subclasses are seen in some patients with repeated infections. Measurements of IgG and specifically IgG4 antibodies have been used in research settings as diagnostic and prognostic tests to determine response to allergy treatments.

**Passive Transfer Of P-X (Prausnitz-Kustner) Test**

This technique involves prick, scratch, or intradermal transfer of serum from a sensitized individual into a non-allergic volunteer. The volunteer is then challenged with the allergen by skin testing. A wheal or a flare response indicates a positive reaction. This procedure is now considered obsolete and has been replaced by the Radioallergosorbent Test (RAST) test.

**Provocative-Neutralization Tests For Food (Or Food Additive Allergy Test)**

This procedure is performed by injecting (intradermal or subcutaneous), or placing under the tongue (sublingual), dilute extracts of the suspected food or inhalant allergen and observing the patient’s response or reaction. A symptomatic response indicates an allergy to that food or inhalant, and the reaction can be neutralized by application of a similar extract of a lesser dilution.

**Rebuck Skin Window Test**

This is a type of skin testing where the skin surface is stripped or broken to cause serious oozing. This area is then covered by a glass plate, coated with the allergen to be tested, and taped in place for 24 hours. At the end of that time the plate is removed, and the cells under the plate and the surrounding skin are checked for any changes. An eosinophilic exudate typical of an allergic reaction appears in the area of the stripped epidermis. The results are very difficult to interpret and are not practical for general use. The procedure is no longer in use.

**ALLERGY TESTS IN THE RESEARCH SETTING**

The following tests are primarily used in the research setting:

**Conjunctival challenge test**

With conjunctival testing, an allergenic extract is placed into the conjunctival sac of the eye followed by observation for redness, itchiness, tearing of the eye, and other similar symptoms. According to the AAAI, these tests are often used in research protocols that require an objective standard for evaluating clinical sensitivity to an allergen.

**Leukocyte Histamine Release Test (LHRT)**

In this testing, leukocytes from the serum of an allergic individual are observed for histamine release in the presence of an antigen. The commercial availability of simplified and automated methods of laboratory analysis has renewed interest in the clinical applications of LHRT in the evaluation of food, inhalant, and drug allergies. The AAAI guidelines for this test indicate it is primarily used in a research setting.
Nasal challenge test

This test provides precise measurements of changes in nasal airway resistance along with observations such as number of sneezes and measurement of inflammatory mediators in the nasal secretions after exposure to an allergen. The more commonly known "sniff test," uses a visual assessment of mucosal swelling and rhinorrhea after a small amount of dry pollen is inhaled.

RATIONALE

EFFECTIVENESS

The following tests have no randomized, controlled clinical trials documenting outcomes and impact on treatment decisions and/or results from clinical trials are inconclusive or contradictory.\(^1\)\(^-\)\(^3\)\(^,\)\(^11\)\(^-\)\(^14\)

- Antigen leukocyte cellular antibody (ALCAT) test
- Applied kinesiology
- Cytotoxic tests
- Electrodermal testing
- Hair analysis
- IgG and IgG4 allergen specific antibody or food test
- Iridology
- Passive transfer or P-X test
- Provocation-neutralization
- Rebuck skin window test

REFERENCES


**CODES**

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<th>Number</th>
<th>Description</th>
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<td>Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; qualitative or semiquantitative, multiple step method</td>
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<td>96902</td>
<td>Microscopic examination of hairs plucked or clipped by the examiner (excluding collection by patient) to determine telogen and anagen counts,</td>
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### Unproven and Inappropriate Diagnostic Tests for Allergic and Immune Deficiency Diseases

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### POLICY HISTORY

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<td>Medical policy renumbered from 2.04.300 to 2.04.500. Added codes: P2031, 82784, 95060, 95065, 95199, 97813, 97814 and 99199. Title changed from “Unproven and Inappropriate Diagnostic Tests for Allergic and Immune Deficiency Diseases” to “Diagnostic Tests for Allergic and Immune Deficiency Diseases of Uncertain Efficacy.”</td>
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