DRAFT Medical Coverage Policy | Allergy Testing

EFFECTIVE DATE: 12|01|2016
POLICY LAST UPDATED: 08|02|2016

OVERVIEW
Allergic or hypersensitivity disorders can manifest themselves as generalized systemic reactions as well as localized reactions in any organ system of the body. Numerous agents, e.g., pollen, mold, dust mites, animal dander, insect stings, foods, or drugs may precipitate allergic or hypersensitivity reactions.

The intent of this policy is to address only those allergy tests that are considered not medically necessary.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
The following tests are considered to be not medically necessary, when performed to establish a diagnosis of allergy, due to insufficient evidence in peer-reviewed literature proving the efficacy of the services.

- Antigen Leukocyte Antibody Test (ALCAT)
- ELISA/Act (Enzyme-linked Immunosorbent Assay/Advanced Cell Test) qualitative antibody testing
- IgG and IgG subclass antibody tests for food allergy
- IgG ELISA, indirect method
- Leukocyte Histamine Release Test (LHRT)
- LMRA (Lymphocyte Mitogen Response Assays) by ELISA/Act

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
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 headaches, 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 nonimmunologic reaction that can lead to a constellation of GI symptoms.

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 diagnose intolerance to foods and other environmental agents. It is a blood test that assesses the response of leukocytes and platelets to a panel of foods and/or other environmental agents, by measuring the change in size and number of cells following exposure to a specific agent.

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.

ALCAT is a blood test that is intended to diagnose intolerance to foods and other environmental agents. There is a lack of published research on the diagnostic accuracy of the test; 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 report improvement in outcomes following use of ALCAT, but it is not possible to determine whether these changes occur as a result of the test itself, versus bias, variation in the natural history of the condition, and/or the placebo effect. Guidelines for the diagnosis of food allergy from the National Institute of Allergy and Infectious Disease do not discuss use of ALCAT. Due to the limitations of the evidence base, and lack of acceptance of the test as a component of standard care by experts in this area, ALCAT is considered not medically necessary for all indications.

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.

Serum IgG Testing - Radioallergosorbent Test (RAST) or Enzyme-linked Immunosorbent Assay (ELISA)
The role of RAST or ELISA measurement of serum IgG in the diagnosis and management of allergic disease has not been established. There are no randomized controlled trials documenting outcomes or impact on treatment decisions. Several evidence-based guidelines have been published, which conclude that IgG testing is not recommended to diagnose food allergies or intolerance.

The American Academy of Allergy, Asthma and Immunology (AAAAI) noted that "Appropriate diagnosis and treatment of allergies requires specific IgE testing (either skin or blood tests) based on the patient's clinical history. The use of other tests or methods to diagnose allergies is unproven and can lead to inappropriate diagnosis and treatment." The AAAAI stated "don't perform unproven diagnostic tests, such as immunoglobulin G (IgG) testing or an indiscriminate battery of immunoglobulin E (IgE) tests, in the evaluation of allergy."

The AAAAI and the American College of Allergy, Asthma and Immunology (ACAAI) indicate IgG and IgG subclass antibody tests for food allergy do have clinical relevance, are not validated, lack sufficient quality control, and should not be performed.

CODING

BlueCHiP for Medicare and Commercial Products
The following codes are not medically necessary:
86001
83516 *
86343

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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, October 2016
Provider Update, March 2016
Provider Update, March 2015
Provider Update, January 2013
Provider Update, January 2012
Provider Update, February 2011
Provider Update, June 2009

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