

(20193)

Medical Benefit		Effective Date: 07/01/14	Next Review Date: 03/19
Preauthorization	No	Review Dates: 03/14, 03/15, 03/16, 03/17, 03/18	

This protocol considers this test or procedure not medically necessary. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Description

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.

Summary of Evidence

There is a lack of published research on the diagnostic accuracy of the ALCAT 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 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. Guidelines for the diagnosis of food allergy from the National Institute of Allergy and Infectious Disease have not discussed the 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.

Policy

The Antigen Leukocyte Antibody Test is considered **not medically necessary** for all indications.

Background

Environmental Illness and Food Intolerance

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, gastrointestinal tract disorders such as irritable bowel syndrome, eczema, chronic fatigue, and migraine headache.¹

Food allergy is the most well-defined type of environmental illness and is estimated to affect 8% of children.² 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 the National Institute of Allergy and Infectious Disease.³

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.² It is hypothesized that physiologic reactions to food may manifest as a range of nonspecific symptoms, such as gastrointestinal 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 gastrointestinal 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.

Antigen Leukocyte Antibody Test

The ALCAT is intended to identify foods and other environmental agents for which an individual may be intolerant. It is not intended to diagnose food allergy.⁴ 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 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, Deerfield Beach, FL) 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 70 to 320.⁴

Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). ALCAT is available under the auspices of the CLIA. Laboratories that offer

LDTs must be licensed by the CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Solomon BA. The ALCAT Test - A guide and barometer in the therapy of environmental and food sensitivities. *Environ Med.* 1992; 9(2):1-6.
2. Gupta RS, Dyer AA, Jain N, et al. Childhood food allergies: current diagnosis, treatment, and management strategies. *Mayo Clin Proc.* May 2013; 88(5):512-526. PMID 23639501
3. NIAID-Sponsored Expert Panel, Boyce JA, Assa'ad A, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-sponsored expert panel. *J Allergy Clin Immunol.* Dec 2010; 126(6 Suppl):S1-58. PMID 21134576
4. Cell Sciences Systems. ALCAT test. n.d.; <https://cellsciencesystems.com/patients/alcat-test/>. Accessed October 19, 2017.
5. Wuthrich B. Unproven techniques in allergy diagnosis. *J Investig Allergol Clin Immunol.* Jul 2005; 15(2):86-90. PMID 16047707
6. Buczylo K, Obarzanowski T, Rosiak K, et al. Prevalence of food allergy and intolerance in children based on MAST CLA and ALCAT tests. *Rocz Akad Med Bialymst.* Jan 1995; 40(3):452-456. PMID 8775289
7. Kaats GR, Pullin D, Parker LK. The short term efficacy of the ALCAT Test of food sensitivities to facilitate changes in body composition and self-reported disease symptoms: a randomized controlled study. *Bariatrician.* 1996; Spring: 18-23. PMID
8. Mylek D. ALCAT Test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system. *Rocz Akad Med Bialymst.* Jan 1995; 40(3):625-629. PMID 8775317