



MASSACHUSETTS

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Medical Policy Antigen Leukocyte Antibody Test

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Policy Number: 673

BCBSA Reference Number: 2.01.93 (For Plan internal use only)
NCD/LCD: NA

Related Policies

None

Policy

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO BlueSM and Medicare PPO BlueSM Members**

The Antigen Leukocyte Antibody Test is **INVESTIGATIONAL** for all indications.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There are no specific CPT codes for this service.

Description

Intolerance of Environmental Agents or Food

Environmental illness refers to a physiologic reaction that is triggered by an exogenous agent, which can be ingested, inhaled, or absorbed 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 (ie, 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 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 a 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, 1 specific food or food group is eliminated from the diet for a specified period, and symptoms are observed. Following the elimination period, a re-challenge 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 Antigen Leukocyte Antibody Test (ALCAT) is intended to identify foods and other environmental agents for which an individual may be intolerant. It is not intended to diagnose food allergies.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 targets 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 then 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) 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 81 to 370.⁴

Summary

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

For individuals who have a suspected intolerance of environmental agents or food who receive the Antigen Leukocyte Antibody Test (ALCAT), the evidence includes a randomized controlled trial and case series. Relevant outcomes are morbid events and medication use. There is a lack of published research on the diagnostic accuracy of ALCAT; 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. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
12/2024	Annual policy review. Policy updated with literature review through August 16, 2024; no references added. Policy statement unchanged. The need for an active policy was affirmed.
12/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2022	Annual policy review. Not medically necessary language refined to investigational in policy statement; intent unchanged. No changes to description, summary, and references.
12/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
11/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
11/2018	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
7/2014	New medical policy describing not medically necessary indications. Effective 7/1/2014.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

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): 512-26. PMID 23639501

3. Boyce JA, Assa'ad A, Burks AW, 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 August 15, 2023.
5. Buczyłko 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*. 1995; 40(3): 452-6. PMID 8775289
6. 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.
7. Mylek D. ALCAT Test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system. *Rocz Akad Med Bialymst*. 1995; 40(3): 625-9. PMID 8775317