

BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	MANUAL: MEDICAL POLICY REFERENCE NO.: MPO-177-0000
EFFECTIVE DATE May 1, 2014	SUBJECT: Antigen Leukocyte Antibody Test (ALCAT)

### **Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy**

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice.

Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease.

Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure.

In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

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#### **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.

#### **BENEFIT POLICY STATEMENT:**

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

## **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, gastrointestinal (GI) 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 IgE 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 Diseases. (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 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.

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 allergic in nature, identification of the inciting agent(s) can be difficult because the symptoms are chronic in nature. 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 of time and symptoms 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 that the process can be lengthy and cumbersome.

ALCAT test: The ALCAT test is intended to identify foods and other environmental agents for which an individual may have intolerance. 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 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.

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 range from 70-320. (4)

**MEDICAL POLICY STATEMENT:**

BCNEPA will not provide coverage for the Antigen Leukocyte Antibody Test (ALCAT) as it is considered not medically necessary for all indications.

**GUIDELINES:**

There are various sizes of ALCAT panels.

**RATIONALE:**

The ALCAT test 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 the ALCAT test, but it is not possible to determine whether these changes occur as a result of 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 (NIAID) do not discuss use of the ALCAT test. 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, the ALCAT test is considered not medically necessary for all indications.

**Practice Guidelines and Position Statements**

There were no clinical practice guidelines identified for the diagnosis and management of food intolerance.

NIAID published guidelines on the diagnosis and management of food allergy in 2010. (3) These guidelines define and distinguish food intolerance from food allergy, but do not provide recommendations for diagnosis and management of intolerance. For the diagnosis of food allergy, the guidelines state that "Tests selected to evaluate food allergy should be based on the patient's medical history and not comprise large general panels of food allergens."

**Medicare National Coverage**

None

**DEFINITIONS:**

N/A

**CODING:**

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- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

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## **PROCEDURE CODES**

83516

**SOURCES:**

1. Solomon B.A. The ALCAT Test - A guide and barometer in the therapy of environmental and food sensitivities. *Environmental Medicine* 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* 2013; 88(5):512-26.
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* 2010; 126(6 Suppl):S1-58.
4. ALCAT test website. Available online at: <http://www.alcat.com/>. Last accessed January 7, 2014.
5. Wuthrich B. Unproven techniques in allergy diagnosis. *J Investig Allergol Clin Immunol* 2005; 15(2):86-90.
6. Buczylko K, Obarzanowski T, Rosiak K et al. Prevalence of food allergy and intolerance in children based on MAST CLA and ALCAT tests. *Roczn Akad Med Bialymst* 1995; 40(3):452-6.
7. Kaats GR PD, 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. *The Bariatrician* 1996; Spring:18-23.
8. Mylek D. ALCAT Test results in the treatment of respiratory and gastrointestinal symptoms, arthritis, skin and central nervous system. *Roczn Akad Med Bialymst* 1995; 40(3):625-9.

**APPROVALS:**

Approved by Vice President, Clinical Operations & Chief Medical Officer:



Signature: \_\_\_\_\_  
(Nina M. Taggart, MA, MD, MBA)

Date of Approval: April 15, 2014

**HISTORY:**

Original Development Date: (05/01/14)

Policy developed by: Medical Policy Department