

(20193)

<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/14	<b>Next Review Date:</b> 03/21
<b>Preauthorization</b>	No	<b>Review Dates:</b> 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

***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.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>With suspected intolerance of environmental agents or food</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Antigen Leukocyte Antibody Test</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Antigen or allergen skin testing</li> <li>Antigen or allergen in vitro assay</li> <li>Elimination dietary changes</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Morbid events</li> <li>Medication Use</li> </ul>

### 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 ALCAT, the evidence includes a randomized controlled trial and case series. The 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 the effects of the technology on health outcomes.

### POLICY

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

## BACKGROUND

### 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 allergies.<sup>1</sup> 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 70 to 357.<sup>1</sup>

## REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments. The ALCAT is available under the auspices of the Clinical Laboratory Improvement Amendments. Laboratories that offer laboratory-developed tests must be licensed by the Clinical Laboratory Improvement Amendments for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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. Cell Sciences Systems. Alcat Test. n.d.; <https://cellsciencesystems.com/patients/alcat-test/>. Accessed August 3, 2018.
2. Solomon BA. The ALCAT Test - A guide and barometer in the therapy of environmental and food sensitivities. *Environ Med.* 1992;9(2):1-6.

3. 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.
4. 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.
5. 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.
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.* Jan 1995;40(3):625-629. PMID 8775317.