Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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Category: Laboratory and Pathology
***Current Policy Effective Date: 1/1/07**

Title: Albumin Cobalt Binding Test

Procedure Code(s): 82045

Description / Background

The diagnosis of acute myocardial ischemia is often difficult due to an unclear initial clinical physical presentation and the lack of rapid, consistently reliable diagnostic tests. Resting electrocardiograms (EKG, ECG), creatine phosphokinase isoenzymes (CK-MB), myoglobin and troponin levels assist in making the diagnosis of myocardial infarction but at times have proven unreliable for detecting acute myocardial ischemia.

The albumin cobalt binding (ACB) test is a quantitative in-vitro diagnostic test used on human serum to detect ischemia-modified albumin (IMA). IMA is a serum biomarker proposed as an aid to the early evaluation of acute coronary syndromes (ACS) in patients who present with chest pain suggestive of cardiac origin. Albumin is abundant in the circulatory system and when a localized ischemic event occurs, the protein is modified in a specific way. This change is rapid and the rise in IMA is evident in about five to six minutes. Therefore, a rise in IMA can be measured almost immediately after an ischemic event and will remain elevated for two to six hours. The ACB test must be used in conjunction with an electrocardiogram (ECG) and troponin test to evaluate whether patients have had a myocardial infarction or an ischemic event which does not result in myocardial injury. At the current time, ACB is not recommended in lieu of clinical assessment and measurement of traditional indicators of myocardial ischemia such as creatine phosphokinase (CPK).

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CPT / HCPCS Level II Codes and Description *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

82045 Albumin; ischemia modified

Diagnoses / Medical Conditions

Chest pain

Medical Policy Statement

The albumin cobalt binding test lacks sufficient sensitivity and specificity to provide clinically relevant information. It does not provide any additional clinical utility in the diagnosis and/or treatment of chest pain over available tests or procedures. The test is therefore investigational and not medically necessary in the diagnosis and/or treatment of chest pain

Rationale

Ischemia modified albumin (IMA) or albumin binding of cobalt (ABC) was first discussed as a clinical test in 2000. It is a simple colorimetric test that requires only a single reagent. As the name implies, a lack of oxygen has a structural effect on albumin, changing its ability to bind various metals, particularly cobalt. IMA has been reported to be positive within minutes of ischemia and remain so for up to several hours, allowing detection before the development of myocardial necrosis (as evidenced by normal levels of creatinine kinase isoenzyme [CK-MB], troponin and myoglobin) in these patients.

Further investigation and studies will be necessary to determine if the albumin cobalt binding test has clinical utility as a diagnostic test to evaluate suspected myocardial ischemia. There is a lack of clinical data demonstrating improved health outcomes (i.e., decreased morbidity or mortality) with the use of this test

Medical Policy Position Summary (Non-clinical summary statement for customer use)

The albumin cobalt binding test is a laboratory test that a physician can do when a patient is complaining of chest pain and the doctor is not sure if the patient is actually having a heart attack. This test is works by measuring how much cobalt is bound to the blood protein albumin. Changes in the structure of albumin occur in several illnesses, including

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heart attacks. The ACB test is not a stand-alone heart attack test but must be used together with an electrocardiogram (ECG) and a blood test for troponin. A normal ACB test with a normal ECG and normal troponin level may give doctors increased confidence that patients can be discharged because they did not have a heart attack. With the ACB test, a cobalt solution is added to a blood sample. Results are read on a chemistry analyzer. In patients with a normal albumin, more cobalt is bound to the albumin, leaving less free cobalt to be detected by the test. In patients with abnormal albumin, less cobalt is bound to the albumin, leaving more free cobalt to be detected by the test.

While this test is safe, there is not enough evidence to show that the use of this test results in a higher ability to rule out a heart attack or improve the course of the patient's illness. This test is considered investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

Related Policies

N/A

Medicare Information

CMS has no written policy regarding this procedure. Medicare pays for most medically necessary laboratory testing.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

References

- Apple, F. S., "Clinical and analytical review of ischemia-modified albumin measured by the albumin cobalt binding test," *Adv Clin Chem*, Volume 39, pp. 1-10, 2005.
- Bar-Or D, Lau E, "Ischemia-Modified Albumin," Department of Trauma Research, Swedish Medial Center, Englewood, Colorado, USA, last updated 1/5/2004.
- Can, M., et al., "Evaluation of effects of ischemia on the albumin cobalt binding (ACB) assay in patients exposed to trauma," *Emerg Med J,* Volume 23, Number 7, pp. 537-0, July 2006.

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- Christenson, Robert H, "Characteristics of an Albumin cobalt Binding Test for Assessment of Acute Coronary Syndrome Patients: Multicenter Study," *Clinical Chemistry,* Volume 47, Number 3, 2001, pp. 464-470.
- *Hayes Alert*, "Blood Test to Assist in Diagnosis of Heart Attack Cleared for Market in the U.S.," March 1, 2003.
- Plaut, David, "Markers of Cardiac Risk; An interest to assess the risk of coronary heart disease, not just cell damage, has emerged," *Advance Newsmagazines*, Volume 15, Issue 5, Page 38, < http://laboratory-manager.advanceweb.com/common/editorialsearch/printerfriendly.aspx?AN=AL_06may1_alp38.html&AD=05-01-2006>, (8/28/06).

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 8/31/06, the date the research was completed.

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Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
12/19/03	12/19/03	1/16/04	Joint policy established
1/7/05	1/7/05	12/22/04	Code update, Routine review
1/1/07	11/1/06	10/21/06	Routine maintenance; policy retired

Next review: This policy is obsolete and will no longer be reviewed.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

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BLUE CARE NETWORK
POLICY: ALBUMIN COBALT BINDING TEST

I. Coverage Determination:

The albumin cobalt binding test is investigational. The peer reviewed medical literature has not yet shown that the ACB test has sufficient diagnostic accuracy to provide clinically relevant information when compared to other available diagnostic procedures for ruling out heart attacks. Benefits are not provided for care, services, supplies, devices, drugs or procedures that are experimental or research in nature.

II. Benefit Information:

N/A

III. Benefit Exclusions:

N/A

IV. Administrative Guidelines:

N/A

V. Effective Date:

Joint policy effective date: 12/19/03, 1/7/05, 1/1/07
Supersedes benefit information of: N/A

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