Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Name of Policy:
Computed Tomography to Detect Coronary Artery Calcification

Policy #: 104
Category: Radiology
Latest Review Date: February 2013
Policy Grade: B

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Electron beam computed tomography (EBCT), also known as ultrafast CT, cine CT, and high-speed CT, is a noninvasive test to measure coronary calcium. It differs from the traditional CT scanner in that it does not use an x-ray tube and it has no moving parts. Instead, it uses an electron beam to produce x-rays generated by a patient’s EKG. It takes 30 to 40 transaxial images of the entire coronary artery tree during a single 20 to 30 second breath hold. These images are taken between heartbeats at 100-millisecond exposure time, which prevents image blurring and allows accurate visualization of very small calcium deposits on the coronary tree. Coronary artery calcium has a close correlation with atherosclerotic plaque burden, which has been shown to be a powerful predictor of future events.

Spiral CT scanning (also referred to as helical CT scanning) also creates images at greater speeds by rotating a standard x-ray tube around the patient such that data are gathered in a continuous spiral or helix rather than in individual slices. While both electron beam CT and spiral CT scanning may be valued as an alternative to conventional CT scanning due to their faster throughput, their speed of image acquisition permits unique imaging of the moving heart.

EBCT has been used to quantify the amount of calcium in the coronary arteries, and thus has been investigated as a tool to screen for CAD in asymptomatic patients and to diagnose obstructive coronary artery disease in symptomatic patients. This would help determine the need for subsequent coronary angiography.

As of 2007, EBCT and multi-detector computed tomography (MDCT) are the primary fast CT methods for measurement of coronary artery calcification. A fast CT study for coronary artery calcium measurement generally takes 10 to 15 minutes and requires only a few seconds of scanning time.

Policy:
Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Effective for dates of service prior to April 1, 2013:
Computed tomography to detect coronary artery calcification does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members’ contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
**Key Points:**
In 2000, the American College of Cardiology and the American Heart Association published a consensus document on EBCT for the diagnosis and prognosis of CAD.

They performed a meta-analysis on the relationship between CHD and calcium prevalence in patients undergoing EBCT and cardiac catheterization to determine the diagnostic accuracy of EBCT in catheterized patients. They also looked at published data to compare the diagnostic characteristics of the available alternative tests to detect CAD. The studies showed a high sensitivity of EBCT for CAD, a much lower specificity, and a predictive accuracy of ~70%. This predictive accuracy is approximately equivalent but not superior to other methods (e.g., SPECT imaging). They noted that the majority of members would not recommend EBCT to diagnose obstructive CAD because of its low specificity (i.e., high percentage of false-positive results).

They also looked at the use of EBCT to screen asymptomatic patients. They stated that since the severity of coronary atherosclerosis is associated with the risk of coronary events, the coronary calcium scores should correlate with the risk for coronary events. Also, for the test to be valuable to screen an asymptomatic patient, it should increase the likelihood of CHD above the probability determined by the available assessments, such as the Framingham risk model.

In further statements by the American Heart Association (AHA) regarding EBCT, the increased predictive value of EBCT of the coronary arteries relative to traditional risk factor assessment is not yet completely defined. EBCT is not a substitute for cardiac catheterization. EBCT measurement of coronary calcium is of no known value in patients who have already had a heart attack or undergone coronary bypass surgery or coronary angioplasty.

The published literature does not completely answer the question of whether the EBCT calcium score is additive to the Framingham score for defining CHD risk in asymptomatic patients. The published literature does not clearly define which asymptomatic people require or will benefit from EBCT.

The authors also noted that the use of EBCT to look at changing calcium scores over time is being studied. There are also studies on the use of EBCT to assess the progression or regression of coronary artery lesions after interventions in patients with modifiable risk factors for CHD.

However, the reproducibility from two scans (interscan reliability) has varied from poor to fair (14%-51% variability).

The 1998 TEC assessment looked at the use of EBCT in symptomatic patients to determine the need for coronary angiography. They stated that there are no studies comparing EBCT with single photon emission computed tomography (SPECT) and stress echocardiography (ECHO). There is no current evidence that shows EBCT improves net health outcomes compared to other noninvasive tests or other management strategies (immediate referral for angiography).

The TEC assessment also looked at the use of EBCT in asymptomatic patients to identify those at high risk to develop CAD. Two studies that reported on the use of EBCT as a screening tool
did not show that EBCT improves on prognostic information from the risk factor models such as Framingham Heart Study Model or the National Cholesterol Education Program II. Neither study compared EBCT to other noninvasive tests such as exercise treadmill testing. There is insufficient evidence to determine whether EBCT is a more effective tool and will result in improved health outcomes.

In 2006, the American Heart Association (AHA) issued a scientific statement on the use of cardiac computed tomography. Most of the document reviewed the utility of calcium scoring for the use of determining prognosis and diagnosis. A large body of evidence was reviewed regarding calcium scoring with clinical recommendations made. No indications received a class I recommendation, i.e., evidence and/or agreement that the procedure is useful and effective. Several indications received a class IIb and class III recommendations. This represents conflicting evidence and/or a divergence of opinion regarding usefulness for IIb and evidence that the procedure or treatment is not useful or possibly harmful for class III.

The 2006 AHA scientific statement also cited studies that did demonstrate an association between calcium scores and coronary artery disease (CAD) events after adjustment for traditional risk factors. Studies have not demonstrated improved clinical outcomes as a result of calcium score screening despite growing evidence that calcium scores are an independent predictor of CAD. This uncertainty of the usefulness of calcium scoring was reflected in their clinical statements.

The American College of Cardiology Foundation (ACCF) and the AHA reviewed the same evidence from the 2006 AHA scientific statement in a 2007 clinical consensus document. It was noted that this type of consensus document represents the best attempt of the ACCF and the AHA to inform clinical practice where rigorous evidence is not yet available. This document cites that the class IIb recommendations “may be reasonable”. Formal grading of evidence and classification of clinical recommendations are not reported in this type of document.

Per the documents cited, studies published have not demonstrated a clear role for EBCT in coronary disease risk stratification in asymptomatic or symptomatic patients, not have any studies shown that clinical outcomes can be favorably altered by the use of screening EBCT. The policy statement remains unchanged at this time.

The number of Computer Tomography (CT) scanners continues to increase as well as the usage of those scanners. It is estimated that more than 62 million CT scans per year are currently done in the United States, including at least 4 million children.

Conventional radiography doses of radiation are much smaller than CT; an abdominal CT delivers about 50 times more radiation to the stomach than conventional x-ray. Data has been gathered on the correlating radiation exposure and subsequent cancer rates from the Japanese survivors of atomic bombs, it is estimated by Brenner and Hall that 1.5% to 2.0% of cancers in the U.S. could be attributable to CT radiation. One study is now underway to gather direct data on CT-associated cancer with results not being available for some years. Per the December 6, 2007, Journal Watch, a recent survey suggested that many physician are unaware of radiation doses and potential risks associated with CT. (Radiology 2004; 231:393)
June 2009 Update
Additional studies published since the last review show similar relationships between coronary artery calcification and coronary disease events. These studies are all qualitatively similar to other studies previously referenced, showing some independent predictive capability of coronary artery calcium score. However, the impact of this predictive information on clinical outcomes is not known.

In a study by Elkeles et al calcium scores were predictive of future coronary events in asymptomatic subjects with type 2 diabetes. There has been one randomized, controlled trial of EBCT published. O’Malley et al randomized 450 subjects to receive EBCT or not, and assessed outcomes one year later for change in Framingham Risk Score. Thus, EBCT was to be used as a guide to refine risk in patients and possibly provide motivation for behavioral change. The study was not powered for clinical endpoints. EBCT did not produce any benefits in terms of a difference in Framingham risk score at one year.

A gap still remains in the literature regarding the incremental predictive capability of coronary calcium beyond traditional risk prediction, and whether this incremental predictive capability can translate into improved decision making and improved patient outcomes. Direct evidence in the form of a clinical trial, or rigorous indirect evidence in terms of decision modeling does not appear to be available. Thus, the essential issue still remains, of how to properly integrate such predictive capability into a coherent practice guideline which can be expected to improve patient outcomes. Therefore, the policy statement remains unchanged.

The Blue Cross Blue Shield Association requested clinical input through Physician specialty Societies and academic Medical Centers. Input was received through 2 Physician specialty Societies and 4 Academic Medical centers on this policy in November 2008. While the various Physician Specialty Societies and Academic Medical Centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the Physician Specialty Societies or Academic Medical Centers, unless otherwise noted. The majority of those providing input agreed with the conclusions of this policy (investigational) as approved in July 2008.

July 2012 Update
Additional studies have defined how the incorporation of calcium scores into risk scores changes risk prediction. In a study by Polonsky et al, incorporation of calcium score into a risk model resulted in more subjects (77% vs. 66%) being classified in either high-risk or low-risk categories. The subjects who were reclassified to high risk had similar risk of CHD events as those who were originally classified as high risk. A study by Elias-Smale et al showed similar findings; reclassification of subjects occurred most substantially in the intermediate risk group (5-10% 5-year risk) where 56% of persons were reclassified.

Also a systematic review by Ferket et al identified 14 guidelines that evaluated diagnostic imaging for asymptomatic coronary artery disease, which included those reviewed above, and additional guidelines from New Zealand and Canada. Ten of the guidelines addressed use of calcium score as a method to improve coronary risk assessment. Four guidelines concluded that
there was sufficient evidence for consideration of its use, and 1 guideline recommended for its use. The only group of patients for whom its use was recommended was that of intermediate-risk patients. For subjects at low risk or high risk, guidelines were unanimous in not advocating calcium scoring

**Key Words:**
Electron beam computed tomography (EBCT), ultrafast CT, cine CT, high-speed CT, single photon emission computed tomography (SPECT), coronary artery disease (CAD), calcium scoring tests, coronary calcium scoring tests, coronary artery calcium, multi-detector computed tomography, MDCT

**Approved by Governing Bodies:**
Imatron Inc. received 510(K) clearance November 1999 from the FDA to market and sell the angiographic capabilities of its Electron Beam Computed tomography (EBCT) scanner also known as Ultrafast Computer Tomography.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

**Current Coding:**
CPT codes:

<table>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>75571</td>
<td>Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium</td>
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HCPCS codes:

<table>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>S8092</td>
<td>Electron beam computed tomography (also known as ultrafast CT, cine CT)</td>
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**Previous Coding:**
CPT codes:

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<tr>
<td>0144T</td>
<td>Computed tomography, heart, without contrast material, including image post processing and quantitative evaluation of coronary calcium <strong>(Code deleted effective January 1, 2010)</strong></td>
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<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>0147T</td>
<td>Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3d image postprocessing; computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass</td>
</tr>
</tbody>
</table>
Proprietary Information of Blue Cross and Blue Shield of Alabama
Medical Policy #104

grafts), with quantitative evaluation of coronary calcium (CPT category III code) (Code deleted effective January 1, 2010)

References:

**Policy History:**
Medical Policy Group, April 2003 (1)
Medical Policy Administration Committee, April 2003
Available for comment May 7-June 20, 2003
Medical Policy Group, April 2007 (1)
Medical Policy Administration Committee, April 2007
Medical Policy Group, December 2007 (1)
Medical Policy Group, June 2009 (1)
Medical Policy Administration Committee, July 2009
Medical Policy Group, July 2012 (4) Updated Key Points and References. Cleaned up coding
Policy remains unchanged.
Medical Policy Group, February 2013 (2) Updated policy with link to CareCore National®
medical policies effective April 1, 2013
Medical Policy Administration Committee, March 2013
Available for comment February15 through March 31, 2013
Medical Policy Group, November 2013 (2): Updated CareCore National® link

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.