Medical Policy

BlueCross BlueShield of Kansas
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Title: Computed Tomography (CT) to Detect Coronary Artery Calcification

See also: *Contrast-Enhanced CTA for Coronary Artery Evaluation*
CTA and MRA of the Chest (excluding the heart)
CTA and MRA of the Head, Neck, Abdomen, Pelvis, Lower Extremity, and Upper Extremity
Cardiac Computed Tomography (CT)

Professional
Original Effective Date: April 2002
Revision Date(s): November 14, 2008
September 18, 2009
Current Effective Date: November 14, 2008

Institutional
Original Effective Date: February 2005
Revision Date(s): November 14, 2008
September 18, 2009
Current Effective Date: November 14, 2008

DESCRIPTION

Electron beam CT (also known as ultrafast CT) uses an electron gun rather than a standard x-ray tube to generate x-rays, thus permitting very rapid scanning. 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 (EBCT) 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. For example, the rapid image acquisition time virtually eliminates motion artifact related to cardiac contraction, permitting visualization of the calcium in the epicardial coronary arteries. EBCT software permits quantification of calcium area and density, which are translated into calcium scores. Calcium scores have been investigated as a technique for detecting coronary artery calcification, both as a technique to diagnostic technique in symptomatic patients to determine the necessity of coronary angiography, or, in asymptomatic patients, as a screening technique for coronary artery disease.

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

The use of computed tomography (CT) to detect coronary artery calcification is considered **investigational**.

RATIONALE

This policy is based in part on a 1998 TEC Assessment (1) that focused on the use of electron beam computed tomography (EBCT) as either a risk stratification technique for asymptomatic patients or as a technique for evaluating the necessity of angiography in symptomatic patients. A literature search was performed in October 2005 to update the policy.

The TEC Assessment (1) offered the following conclusions.

1. As a screening technique for asymptomatic patients

Two distinct studies reported on the use of EBCT to identify individuals at high risk for coronary artery disease (CAD). Neither study showed that EBCT improved on the prognostic information from risk-factor models such as the Framingham Heart Study or the National Cholesterol Education Program III (NCEP III). Similarly, neither study compares EBCT against other noninvasive tests such as exercise treadmill testing (ETT). Despite the ease with which EBCT may be performed, existing evidence did not establish that EBCT results in improved health outcomes by improving prognostic information.

2. As a diagnostic study in symptomatic patients

While EBCT is an effective method of selecting symptomatic patients for angiography, no studies make direct comparison with other noninvasive tests such as single-photon computed tomography (SPECT) or echocardiography. Evidence suggested that EBCT was not as effective as SPECT. Evidence was inadequate to determine whether EBCT is as effective as other commonly used tests such as echocardiography.

In 2000, the American College of Cardiology and the American Heart Association (ACC/AHA) jointly issued a consensus document (2) on the use of EBCT. Regarding the use of EBCT in asymptomatic patients, the executive summary included the following statements:

Because the severity of coronary atherosclerosis is known to be associated with risk of coronary events, coronary artery calcium scores should likewise correlate with risk for coronary events. However, for a test to be most valuable when asymptomatic patients are screened, it should increase the likelihood of coronary heart disease above the probability determined by standard and readily available assessments, such as the Framingham risk model….The published literature does not completely answer the question of whether the EBCT calcium score is additive to the Framingham score for defining [coronary heart disease (CHD)] risk in asymptomatic patients…. Selected use of coronary calcium scores may be appropriate when a physician evaluates a patient with intermediate coronary disease risk. However, the published literature does not clearly define which asymptomatic

people require or will benefit from EBCT. Additional appropriately designed studies of EBCT for this purpose are strongly encouraged.

Regarding the use of EBCT in symptomatic patients, the ACC/AHA executive summary included the following statement: "The majority of the members of the Writing Group would not recommend EBCT for diagnosing obstructive coronary artery disease because of its low specificity (high percentage of false-positive results), which can result in additional expensive and unnecessary testing to rule out a diagnosis of coronary artery disease." The 1999 ACC/AHA Coronary Angiography Guideline committee reached a similar conclusion.

2005 Policy Update

Since the release of the ACC/AHA Consensus Document in 2000, several potentially relevant publications were identified that examined screening in asymptomatic individuals.

Although it had been well established previously that calcium scores predicted future coronary events, studies showing incremental predictive value beyond that of standard risk prediction had been lacking. Recent prospective studies have shown evidence for predictive capacity of calcium scores in addition to assessment of traditional risk factors. In a study of 1,029 asymptomatic adults with at least 1 coronary risk factor, Greenland et al. (3) showed that a calcium score of greater than 300 predicted increased risk of cardiac events within Framingham risk categories. A study by Arad et al. (4) showed similar findings in a population-based sample of 1,293 subjects who had both traditional risk factors and calcium scores evaluated at baseline. A study by Taylor et al. (5) studied the association of the Framingham risk score and calcium scores in a young military population (mean age 43 years). Although only 9 acute coronary events occurred, calcium scores were associated with risk of events while controlling for the risk score. LaMonte et al. (6) also analyzed the association of calcium scores and CHD events in 10,746 adults. In this study, coronary risk factors were self-reported. During a mean follow-up of 3.5 years, 81 CHD events occurred. Similar to the other studies, the relationship between calcium scores and CHD events remained after adjustment for other risk factors.

Although a growing body of literature now addresses the relationship of traditional risk factors, calcium scores, and risk of coronary heart disease, more knowledge is needed about how calcium scores should be integrated into treatment guidelines. Current treatment guidelines for coronary disease prevention recommend specific treatment based on prediction of coronary disease risk. Thus, solid information is needed on how such a risk predictor produces accurate predictions. The cited studies enrolled different populations, assessed different traditional risk factors, and assessed different coronary disease outcomes. Different calcium score cutoffs were analyzed in the studies. Given the variation in the studies, it is difficult to know the magnitude of increased risk conferred by a given calcium score. The results of the study by Greenland et al. (3) would suggest that a high calcium score as defined as a score greater than 300 does not change risk appreciably for those with Framingham risk scores less than 10% or greater than 20%. Given that there is no direct evidence that risk stratification using calcium scores in addition to traditional risk assessment improves patient outcomes, a consensus approach that integrates existing

evidence with a modeling approach to predicting patient outcomes would aid in determining whether EBCT is of value.

The U.S. Preventive Services Task Force, in its 2004 revision regarding recommendations for screening for CHD (7), found insufficient evidence to recommend for or against routine screening with electrocardiography (ECG), ETT, or EBCT scanning for coronary calcium for either the presence of severe coronary artery stenosis or the prediction of CHD events in adults at increased risk for CHD events.

In summary, the additional studies published since the 1998 TEC Assessment did not yet establish a clear role for EBCT in coronary disease risk stratification in asymptomatic patients, nor have any studies shown that clinical outcomes can be favorably altered by the use of screening EBCT.

The 2005 policy update did not identify any new studies that evaluated the use of EBCT for diagnosing CAD in symptomatic patients that altered the medical policy statement.

2006-2007 Update

In 2006, the American Heart Association (AHA) issued a scientific statement (8) on the use of cardiac CT. Most of the document reviewed the utility of calcium scoring for the use of determining prognosis and diagnosis. In addition to reviewing a large body of evidence regarding calcium scoring, clinical recommendations were also offered. 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 recommendation, which means that there is conflicting evidence and/or a divergence of opinion regarding usefulness or efficacy. The "b" qualifier indicates usefulness/efficacy is less well established. The indications that received a IIb recommendation were:

- Patients with chest pain with equivocal or normal ECGs and negative cardiac enzymes
- Determining the etiology of cardiomyopathy
- Symptomatic patients, in the setting of equivocal treadmill or functional tests
- Asymptomatic patients with intermediate (e.g., 10–20% 10-year risk) risk of CAD

Four indications received a class III recommendation, which means that there is evidence that the procedure or treatment is not useful or possibly harmful. These indications were:

- Low-risk (<10% 10-year risk) and high-risk (>20% 10-year risk) asymptomatic patients
- Establishing the presence of obstructive disease for revascularization in asymptomatic persons
- Serial imaging for assessment of progression of coronary calcification
- Hybrid nuclear and CT imaging

The 2006 AHA scientific statement (8) also cited several other studies showing an association between calcium scores and coronary artery disease (CAD) events after adjustment for traditional risk factors. The report recognized that despite growing evidence that calcium scores are an independent predictor of CAD, studies have not demonstrated

improved clinical outcomes as a result of calcium score screening. This scientific statement reflected these uncertainties in the utility of calcium scoring in their clinical guideline statements.

A 2007 clinical consensus document co-written by the American College of Cardiology Foundation (ACCF) and the AHA (9) reviewed much of the same evidence as the 2006 AHA scientific statement. It should be noted that this type of consensus document represents the best attempt of the ACCF and AHA to inform clinical practice where rigorous evidence is not yet available. Thus formal grading of evidence and classification of clinical recommendations are not reported in this type of document. This document essentially concludes that the indications receiving a IIb recommendation in the 2006 scientific statement "may be reasonable…."

In summary, studies published do not establish a clear role for detection of coronary artery calcification by CT in coronary disease risk stratification in asymptomatic or symptomatic patients, nor have any studies shown that clinical outcomes can be favorably altered by the use of computed-tomography-based determination of coronary artery calcification in screening for CAD. Guideline statements based on this evidence reflect the uncertain role of EBCT by not giving strong endorsement to the test.

2008 Update

Additional studies published since the last policy update show similar relationships between coronary artery calcification and coronary disease events (10, 11). 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.

2009 Update

Additional studies published since the last policy update are similar to prior studies showing a graded association between coronary calcium scores and coronary disease events. In a study by Elkeles et al., (12) calcium scores were predictive of future coronary events in asymptomatic subjects with type 2 diabetes.

There has been 1 randomized, controlled trial of EBCT published. O'Malley et al. (13) randomized 450 subjects to receive EBCT or not, and assessed outcomes 1 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 1 year.

Editorialists remind us that more data are needed to determine when scans such as these add incremental prognostic value to standard assessments and whether calcium scoring will lead to improved treatment and outcomes. (14, 15)

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.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received through 2 physician specialty societies and 4 academic medical centers on this policy (the version approved in July 2008) 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.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) 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 of these services as it applies to an individual member.

CPT/HCPCS

0144T	Computed tomography, heart, without contrast material, including image post processing and quantitative evaluation of coronary calcium
0147T	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 grafts), with quantitative evaluation of coronary calcium
0149T	Computed tomography, heart, with contrast material(s), including noncontrast images, if performed, cardiac gating and 3D image postprocessing; cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts), with quantitative evaluation of coronary calcium
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

REVISIONS

11-14-2008	▪ Changed title from Electron Beam Computerized Tomography (EBCT) Screening for Cardiovascular Calcium Deposits also known as Ultrafast CT, CT angiography and CINE CT to Computed Tomography to Detect Coronary Artery Calcification. ▪ Added a rationale section to the policy. ▪ In Coding section, added CPT codes: 0144T, 0147T, 0149T.
09-18-2009	In Header: ▪ Added reference policies: Contrast-Enhanced CTA for Coronary Artery Evaluation, CTA and MRA of the Chest (excluding the heart), CTA and MRA of the Head, Neck, Abdomen, Pelvis, Lower Extremity, and Upper Extremity, and Cardiac Computed Tomography (CT).
	Updated Rationale and References sections

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