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Medical Policy Manual

Topic: Computed Tomography to Detect Coronary Artery Calcification

Date of Origin: January 1996

Section: Radiology

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Policy No: 6

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

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 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, in both symptomatic patients to determine necessity of coronary angiography and 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 10-15 minutes and requires only a few seconds of scanning time.

Note: The use of contrast-enhanced computed tomographic angiography (CTA) for coronary artery evaluation including evaluation of congenital coronary artery anomalies, evaluation of CAD in an emergent setting, or for the diagnosis of CAD is addressed separately in Radiology, Policy No. 46.

MEDICAL POLICY CRITERIA

The use of computed tomography to detect and quantify coronary artery calcification is considered **investigational**.

SCIENTIFIC EVIDENCE[1]

This policy addresses the use of electron beam computed tomography (EBCT) for two main indications, namely, as a screening technique for coronary artery disease (CAD) in asymptomatic individuals or for evaluating the necessity of angiography in symptomatic patients. Each indication is discussed separately below.

EBCT as a Screening Technique for Asymptomatic Patients

Background

The use of EBCT in asymptomatic patients was described in the executive summary of a 2000 joint statement from the American College of Cardiology and the American Heart Association (ACC/AHA) as follows:[2]

> 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.

Literature Appraisal

Technology Assessment

The policy for EBCT as a screening technique was initially based on a 1998 BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment, which offered the following analysis and conclusions:[3]

- 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 upon 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 compared EBCT against other non-invasive tests such as exercise treadmill testing. Despite the ease with which EBCT may be performed, existing evidence did not establish that EBCT resulted in improved health outcomes by improving prognostic information.

Since the 1998 TEC Assessment was published, several potentially relevant publications were identified that examined screening in asymptomatic individuals. Although it was well established previously that calcium scores predicted future coronary events, studies showing incremental predictive value beyond that of standard risk prediction were lacking. Recent prospective studies demonstrated evidence for predictive capacity of calcium scores in addition to assessment of traditional risk factors, as shown in the following examples.

Systematic Reviews and Meta-Analyses

In 2012, Whelton et al. published a systematic review with meta-analysis of RCTs that evaluated the impact of coronary calcium scores on cardiac risk profiles and cardiac procedures.[4] Four trials[5-8] with a total of 2,490 participants met inclusion criteria; the individual trials ranged in size from 50-1,934 patients. The authors pooled data on the impact of calcium scores on blood pressure from 4 trials, low-density lipoprotein from 3 studies, and high-density lipoprotein from 2 studies. Pooled analysis did not show a significant change in any of these parameters as a result of calcium scores. Similarly, in 4 studies that looked at the rates of smoking cessation following calcium scores, there was no significant change found. There were 2 studies that included rates of coronary angiography and 2 studies that included rates of revascularization. Pooled analysis of these studies did not show a significant change following measurement of coronary calcium.

Randomized Controlled Trials (RCTs)

No RCTs have been published since the Whelton et al. meta-analysis summarized above.

Nonrandomized Trials

- In a study of 1,029 asymptomatic adults with at least one coronary risk factor, Greenland and colleagues showed that a calcium score of >300 predicted increased risk of cardiac events within Framingham risk categories.[9]
- A study by Arad and colleagues showed similar findings in a population-based sample of 1,293 subjects who had both traditional risk factors and calcium scores evaluated at baseline.[10]
- A study by Taylor and colleagues studied the association of the Framingham risk score and calcium scores in a young military population (mean age 43 years).[11] Although only nine acute coronary events occurred, calcium scores were associated with risk of events while controlling for the risk score.
- LaMonte and colleagues also analyzed the association of calcium scores and coronary heart disease (CHD) events in 10,746 adults.[12] 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.
- Other studies showed similar findings.[13-15]

Additional studies have investigated 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.[16] 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.[17]

Conclusion

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. Although a growing body of literature now addresses the relationship of traditional risk factors, calcium scores, and risk of coronary heart disease, the additional studies published since the 1998 TEC Assessment do 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. It is difficult to determine the magnitude of increased risk conferred by a given calcium score in the cited studies due to the between-study heterogeneity in the following areas:

- Patient populations enrolled
- Risk factors assessed
- Coronary disease outcomes measured
- Calcium score cutoffs

Thus, more knowledge is needed about how calcium scores should be integrated into treatment guidelines.

EBCT as a Diagnostic Study in Symptomatic Patients

Background

In certain clinical situations such as patients presenting with chest pain or other symptoms, it is uncertain whether the symptoms are potentially due to CHD. Coronary calcium measurement has been proposed as a method that can rule out CHD in certain patients if the coronary calcium value is zero. Since coronary disease can only very rarely occur in the absence of coronary calcium, the presence of any coronary calcium can be a sensitive but not specific test for coronary disease. False positives occur because the calcium may not be causing ischemia or symptoms. The absence of any coronary calcium can be a specific test for the absence of coronary disease and direct the diagnostic workup toward other causes of the patient's symptoms. In this context, coronary calcium measurement is not used to make a positive diagnosis of any kind but as a diagnostic "filter" used to rule out an atherosclerotic cause for the patient's symptoms.

In order to demonstrate that use of calcium scores improves the efficiency or accuracy of the diagnostic workup of symptomatic patients, rigorous studies that define exactly how coronary calcium scores are used in combination with other tests in the triage of patients would be necessary. Study designs need to explicitly evaluate diagnostic strategies that compare one strategy which uses calcium scores to an alternative which does not use calcium scores. Ideally, patient outcomes and resource utilization would need to be prospectively evaluated.

Literature Appraisal

Technology Assessment

The 1998 BCBSA TEC Assessment determined that while EBCT was an effective method of selecting symptomatic patients for angiography, no studies made direct comparisons with other non-invasive tests such as single photon computed tomography (SPECT) or echocardiography.[3] The evidence suggested that EBCT was not as effective as SPECT. The TEC Assessment concluded that evidence was inadequate to determine whether EBCT was as effective as other commonly used tests such as echocardiography.

Both the BCBSA TEC Assessment and the 2000 ACC/AHA Expert Consensus Document, summarized below, focused on the use of EBCT for detecting coronary artery calcification. While spiral CT scanning has been used for the same purpose, there are minimal data regarding this application and there are inadequate data to determine whether calcium scores derived from spiral CT imaging are equivalent to those derived from EBCT imaging. Most importantly, limitations in the data regarding EBCT noted in both the TEC Assessment and ACC/AHA document also apply to spiral CT scanning.

Clinical Trials

Since the TEC Assessment and the ACC/AHA statement, there continues to be insufficient evidence to determine the clinical utility for this testing in symptomatic patients. For example, a study by Laudon et al. in the emergency department setting, 51% (133/263) of patients with chest pain and low-to-moderate probability of CAD had calcium scores of zero.[18] One of these patients was found to actually have coronary disease. The others were presumed to not have coronary disease, and it is claimed that these patients could have been safely discharged from the emergency department. However, the study was not rigorous in its methods regarding the alternative workup of potential coronary artery disease in the emergency department or in the long-term follow-up of patients.

Clinical Practice Guidelines

<u>EBCT as a Screening Technique for Asymptomatic Patients</u>

- The 2000 ACC/AHA joint consensus document[2] on the use of EBCT for the diagnosis and prognosis of coronary artery disease concluded that, "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 risk in asymptomatic patients. Selected use of coronary calcium scores when a physician is faced with a patient with intermediate coronary disease risk may be appropriate. 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."

- In 2006, the American Heart Association (AHA) issued a scientific statement on the use of cardiac computed tomography.[19] 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. Cardiac CT in asymptomatic patients with intermediate (e.g., 10–20% 10-year risk) risk of coronary artery disease received a class IIb recommendation, defined as having conflicting evidence and/or a

divergence of opinion regarding usefulness or efficacy. The “b” qualifier indicates usefulness/efficacy is less well established.

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 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 reviewed much of the same evidence as the 2006 AHA scientific statement.[20] 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 concluded that the indications receiving a IIb recommendation in the 2006 scientific statement “may be reasonable”.

- In 2009, the U.S. Preventive Services Task Force (USPSTF) issued recommendations regarding the use of nontraditional or novel risk factors in assessing CHD risk in asymptomatic persons.[21,22] Calcium score was 1 of 9 risk factors considered in the report. They concluded that the current evidence is insufficient to assess the balance of benefits and harms of using any of the nontraditional risk factors studied to assess risk of coronary disease in asymptomatic persons. In their focused review of 5 studies, which they judged to have valid study designs, they found wide variation in the estimates of the risk ratio for higher calcium scores. Higher quality studies had lower relative risks for a given difference in calcium score. This review disagrees with an ACCF/AHA 2007 clinical consensus document[20] regarding the effect of calcium scores on reclassifying risk of coronary disease. Rather than the 4 studies that the ACCF/AHA document claims provides information about reclassification, the USPSTF report only found one such study.

  The USPSTF recommends against routine CHD screening for either the presence of severe coronary artery stenosis or for the prediction of CHD events in the following patients:[23]
  - Adults at low risk for CHD events. This recommendation was rated D, defined as having at least fair evidence that the service is ineffective or that harms outweigh benefits.
  - Adults at increased risk for CHD events. This was rated as an I recommendation, defined as because evidence is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

- Recommendations on calcium scoring from the 2010 ACCF/AHA Guidelines[24] are as follows:

(Evidence level B is defined as limited populations evaluation. Data derived from a single randomized trial or nonrandomized studies.)

- Class IIa: Additional studies with focused objectives needed

  Measurement of CAC [coronary artery calcification] is reasonable for cardiovascular risk assessment in asymptomatic adults at intermediate risk (10% to 20% 10-year risk). (Level of Evidence: B)

- Class IIb: Additional studies with broad objectives needed; additional registry data would be helpful

  Measurement of CAC may be reasonable for cardiovascular risk assessment in persons at low to intermediate risk (6% to 10% 10-year risk). (Level of Evidence: B)

- Class III: No benefit

  Persons at low risk (<6% 10-year risk) should not undergo CAC measurement for cardiovascular risk assessment. (Level of Evidence: B)

- The 2011 position statement on atherosclerotic cardiovascular disease screening in adults from the American College of Preventive Medicine (ACPM) states that the ACPM does not recommend routine screening, including EBCT, of the general adult population.[25] The statement also notes a lack of evidence that coronary calcium scores improve the prediction of CHD in populations at intermediate risk, stating that more population-based studies in the intermediate risk population.

<u>EBCT as a Diagnostic Study in Symptomatic Patients</u>

- Regarding the use of EBCT in symptomatic individuals, the 2000 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."[2] The 1999 ACC/AHA Coronary Angiography Guideline committee reached a similar conclusion.

- As noted above, the 2006 AHA scientific statement[19] reviewed the utility of calcium scoring for the use of determining prognosis and diagnosis. Like the recommendations for asymptomatic patients, no indications for symptomatic patients received a class I recommendation. The indications in symptomatic patients that received a IIb recommendation were:

  - Patients with chest pain with equivocal or normal electrocardiograms and negative cardiac enzymes

  - Determining the etiology of cardiomyopathy

  - Symptomatic patients, in the setting of equivocal treadmill or functional tests

- A 2007 clinical consensus document co-written by the American College of Cardiology Foundation (ACCF) and the AHA[20] 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 concluded that the indications receiving a IIb recommendation in the 2006 scientific statement “may be reasonable”.

The consensus document concluded that calcium scores have similar sensitivity and specificity to other tests such as exercise single-photon emission computed tomography (SPECT) and stress echocardiography for the diagnosis of anatomic obstructive CHD. It is difficult to determine the validity of these diagnostic performance characteristics given the possible referral and confirmation biases. If the performance of the reference standard for coronary disease such as angiography is based upon the results of the diagnostic tests under study, diagnostic test characteristics are biased.

Summary

There is extensive evidence on the predictive value of coronary artery calcium screening for cardiovascular disease, and this evidence demonstrates that scanning has incremental predictive accuracy above traditional risk factor measurement. High-quality evidence is lacking comparing the use of coronary artery calcium screening to other methods of enhanced risk prediction, and as a result, there is uncertainty as to which methods are preferred in specific populations. Limited evidence from clinical trials suggests that scanning may lead to improved risk factor profiles, but this finding has not been consistent and methodologic limitations preclude definitive conclusions on this question.

Evidence-based guideline statements regarding calcium score measurement give, at best, reserved recommendations in favor of the use of electron beam computed tomography (EBCT) and recognize the incomplete evidence base that supports those recommendations. Review of several guidelines shows disagreement regarding the utility of calcium score measurement. The US Preventive Services Task Force (USPSTF) review highlights the inconsistency of the relative risk of coronary disease associated with calcium scores, thus making risk estimates based on it imprecise. Because of the lack of high-quality evidence demonstrating improved outcomes and the lack of strong recommendations from authoritative sources, the use of computed tomography (CT) to detect coronary artery calcification is considered investigational.

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Ultrasonographic Measurement of Carotid Artery Intima-Media Thickness as an Assessment of Atherosclerosis, Radiology, Policy No. 37

Whole Body CT Screening, Radiology, Policy No. 40

Contrast Enhanced Computed Tomographic Angiography (CTA) for Coronary Artery Evaluation, Radiology, Policy No. 46

CODES	NUBMER	DESCRIPTION
CPT	75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
HCPCS	S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)