

Health Technology Clinical Committee Findings and Coverage Decision

Topic: Coronary Artery Calcium Scoring (CACS)

Meeting Date: November 20th, 2009

Final Adoption:

Number and Coverage Topic

20091120A – Coronary Artery Calcium Scoring

HTCC Coverage Determination

Cardiac Artery Calcium Scoring is a **non-covered benefit**.

HTCC Reimbursement Determination

- ❖ **Limitations of Coverage**
 - Not Applicable
- ❖ **Non-Covered Indicators**
 - Coronary Artery Calcium Scoring
- ❖ **Agency Contact Information**

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The Coronary Artery Calcium Scoring (CACS) topic was selected and published in December 2008 to undergo an evidence review process. Heart disease is the leading cause of death and disability in US: with 700,000 deaths. The most common heart disease in the United States is coronary artery disease (CAD), which can lead to heart attack. CAD is a narrowing of one or more coronary arteries that result in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries. CAD may be asymptomatic or lead to chest pain (angina), heart attack, myocardial infarction (MI), or death. Cardiac related diagnostic tests include both non-invasive and invasive tests. Non-invasive tests include – stress echocardiograms: tests that compare blood flow with and without exercise and visualize the heart; single-photon emission computed tomography (SPECT), also known as nuclear stress testing or myocardial perfusion imaging; and CT angiography with or without calcium scoring using 3D imaging to visualize the heart. Invasive tests include – the “gold” standard is the conventional coronary angiography (CCA) which involves placement of a catheter and injection of contrast material into a large artery or vein, followed by 2-dimensional visualization with x-rays.

Cardiac calcium scoring uses a CT to check for the buildup of calcium in plaque on the coronary arteries. This test identifies and quantifies a marker of coronary disease (plaque), believed to detect earlier state of CAD. Cardiac calcium scoring uses CT to check for the buildup of calcium in the coronary arteries. Calcium is associated with atherosclerosis and is one marker of CAD. However, coronary calcium is not present in all atherosclerotic plaques and its relevance to risk and treatment is unclear. CACS scans the heart using CT by taking imaging “slices” of the heart. Calcium scores increase with age particularly after 50 years in men and 60 years in women.

In August 2009, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Coronary Artery Calcium Scoring report is 94 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on November 20th, reviewed the report, including peer and public feedback, and heard agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on coronary artery calcium scoring (CACS) has been collected and summarized.

- Heart disease is a prevalent and burdensome disease, and the leading cause of death in the US. Identifying which patients are at risk of major cardiac events is therefore important, but currently difficult. Symptoms of CAD (e.g. chest pain) have poor correlation to risk. Diagnostic testing can be used to help confirm or refute a suspicion of clinically significant CAD. CACS provides anatomical information (not functional) on the amount of calcium, a marker of CAD in the heart and coronary arteries.
- CACS role is unclear: it is not currently proposed or likely to be a replacement for conventional coronary angiography (CCA) based on test performance characteristics and lack of consensus about appropriate thresholds. Literature related to clinical or treatment outcomes generally focus on use for triaging symptomatic patients and that CACS may reduce the use of conventional coronary angiography.
- The clinical committee acknowledged that the population under consideration is not screening, but patients with suspected CAD. The committee discussed that this could be either asymptomatic based on history or other risk factors or symptomatic, though later concluded that most available evidence related to symptomatic patients.
- The calcium scoring process isn't automatic, experience is needed for scoring.
- A vast majority of scanners can provide a calcium score. Guidelines in 1996 provided minimum scanner requirements for resolution.

2. Is the technology safe?

The committee concludes that the comprehensive evidence reviewed is unclear in showing that calcium scoring is safe. Key factors to the committee's conclusion included:

- The committee agreed with the evidence report and current guidelines, in clinical practice, this is not a stand-alone test: it is an additional test with additional radiation and incidental findings risks. If used as triage, some individuals may not have subsequent, more invasive test, but larger group will have radiation.
- The committee agreed that there is harm in radiation exposure that is cumulative, but good evidence to quantify the risk are currently not known.
- The committee acknowledged the evidence report information regarding incidental findings, and agreed that current evidence is inconclusive.

3. Is the technology effective?

The committee concludes that the comprehensive evidence reviewed shows that Calcium Scoring is not more effective for treatment of coronary artery disease (CAD).

- The committee agreed with the evidence report and found that CACS specificity and reliability are high for CACS, though sensitivity is low and like other tests, accuracy

is affected by the disease prevalence. While accuracy and reliability are critical, they are only a first step as to whether a test is effective. The committee also agreed that there is no evidence to establish a clinically important threshold: increase in calcium does indicate disease, but the correlation to severity of stenosis is not established – which is key in a disease that is widely prevalent, where serious events occur in some, but are difficult to predict.

- In evaluating effectiveness, the most rigorous question is whether substituting this test, instead of a current diagnostic, results in better treatment and outcomes. In this case, the evidence is insufficient and current clinical practice does not support using this test alone or as a substitute.
- The other diagnostic effectiveness key question discussed by the committee is whether there is evidence that using this test as an added tool to current strategy provides a benefit (clinical or cost). The remaining analysis relate to answering this question.
- One potential use would be in ER where symptomatic patient at low to intermediate risk - could rule out disease. This use would require CACS of 0 value, so the specificity goes down, and at least a 5% group would still receive a negative test, but would have disease. One small retrospective study looked at 4 month follow up on 100 patients in ED where CACS score was taken, along with other tests and concluded that a score of 0 could permit a discharge. CACS studies did not include any RCT or higher quality observational trials to explicitly test what different clinical or treatment choices are made. Clinical expert noted that usually need a functional test to confirm.
- The committee noted national guidelines do not endorse use of Calcium scoring, though some have permissive statements for use of the test.

4. Is the technology cost-effective?

The committee concludes that the comprehensive evidence review shows no published good quality evidence on Calcium Scoring.

- Committee acknowledged the state agency costs for coronary diagnostics of nearly \$7 million per year, and this would likely be an additional test and cost.
- The evidence report adequately summarized the poor cost evidence based on assumptions not current valid.
- Further, cost per correct diagnosis is a function of prevalence of disease, and CAD is highly prevalent, though the real detection issue is major adverse outcomes, not disease presence. Overall spend for reduction or prevention of negative patient outcome (here major cardiac event) is more appropriate measurement criteria.

5. Evidence about the technology's special populations, patient characteristics and adjunct treatment

- The committee agreed that no compelling evidence exists in the sub groups (diabetic, gender and age) to conclude that this test was more (or less) effective in those special populations.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare coverage decision and expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services – no national Medicare policy.
 - CMS Regional Coverage (Washington and Alaska) – the local regional CMS had determined that there is a lack of evidence of the medical necessity for quantitative evaluation of coronary artery calcium.
- Guidelines – a search of the National Guideline Clearinghouse (NGC) returned 4 potential guidelines on Calcium Scoring. The following provides a summary of the guidelines that were most relevant:
 - (1) American College of Cardiology Foundation (ACCF) – Clinical Expert Task Force – lack of evidence from studies comparing CAC measurement to alternative risk assessment techniques for moderate risk patients. No clear evidence is available indicating that additional non-invasive testing in patients with high calcium scores will result in more appropriate selection of treatment over the currently recommended preventative medical therapies. Patients with atypical cardiac symptoms may benefit from CAC testing to help exclude the presence of obstructive CAD.
 - (2) American Heart Association, 2006 – conflicting evidence and/or a divergence of opinion regarding its usefulness was found for the following indications: symptomatic patients with chest pain with equivocal or normal electrocardiograms and negative cardiac enzymes; determining the etiology; symptomatic patients in the setting of ambiguous stress tests; and asymptomatic patients with intermediate risk of CAD. Furthermore, the report stated 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.
 - (3) American Heart Association, 2009 – the following are the minimum requirement which should be met in scanning for coronary artery calcium (CAC): use of an EBCT scanner or a 4-level (or greater) MDCT scanner; cardiac gating; prospective triggering for reducing radiation exposure; a gantry rotation of at least 500 ms; reconstructed slice thickness of 2.5 to 3 mm to minimize radiation in asymptomatic persons (and to provide consistency with established results); early to mid-diastolic gating; and equipment or nuclear material in cardiac imaging should be appropriately utilized to maintain patient doses as low as reasonable achievable but consistent with obtaining the desired medical information.
 - (4) American College of Radiology (ACR) Appropriateness Criteria, 2008 – for assessment of chronic chest pain in patients with low to intermediate probability of CAD: CT coronary calcium scoring received a rating of 3 (1 = least appropriate, 9 = most appropriate); a score of zero may be useful in excluding cardiac etiology; and relative radiation level is considered to be medium.
 - (5) American College of Cardiology (ACC) and American Heart Association (AHA) for the diagnosis and prognosis of CAD, 2000 – the following are a summary of interpretations and recommendations for cardiac CT scanning and CACS: a negative test (score = 0) makes the presence of atherosclerotic plaque, including unstable or vulnerable plaque, highly unlikely; a negative test is consistent with a low risk of a cardiovascular event in the next two to five years; a positive test (CAC > 0) confirms the presence of a coronary atherosclerotic plaque; the greater the amount of coronary calcium, the greater the atherosclerotic burden in men and women, irrespective of age;

and CAC measurement can improve risk predication in conventional intermediate-risk patients, and CAC plaque scanning should be considered in individuals at intermediate risk for a coronary event for clinical decision-making with regard to refinement of risk assessment.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, input from a subject matter expert, agency and state utilization information. The committee concluded that the current evidence on Calcium Scoring demonstrates that there is insufficient evidence to cover the use of Coronary Artery Calcium Scoring (CACS). The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee found that Calcium Scoring would be an additive test that was not supported by sufficient evidence regarding whether it is safe, cost-effective and effectively diagnoses and prevents major cardiac events thus helping patients.

Based on these findings, the committee voted 10 to 0 to not cover Calcium Scoring.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to gather and assess the quality of the latest medical evidence using a scientific research company and take public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC), determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. Selected technologies are considered for re-review on the basis of new evidence.