Health Technology Clinical Committee Findings and Coverage Decision

Topic: Coronary Computed Tomographic Angiography
Meeting Date: November 14, 2008
Final Adoption: May 8, 2009

Number and Coverage Topic

20081114A – Coronary Computed Tomographic Angiography for detection of Coronary Artery Disease.

HTCC Coverage Determination

Coronary Computed Tomographic Angiography (CCTA) is **covered benefits with conditions** consistent with the criteria identified in the reimbursement determination**.**

HTCC Reimbursement Determination

❖ Limitations of Coverage

1) Patients with low to intermediate risk of coronary artery disease;
2) For investigation of acute chest pain in an emergency department or hospital setting; and
3) Using Computed Tomography machines with 64-slice or better capability.

❖ Non-Covered Indicators

Patients who are asymptomatic or at high risk of coronary artery disease;

CCTA used for coronary artery disease investigation outside of the emergency department or hospital setting; and

CT scanners that use lower than 64- slice technology.

❖ Agency Contact Information

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

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Computed Tomographic Angiography Background

The Computed Tomographic Angiography topic was selected and published in August 2007 to undergo an evidence review process. Heart disease is the leading cause of death and disability in the US: with 700,000 deaths. The most common heart disease in the US 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. *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. *Invasive tests include:* The "gold" standard is the conventional coronary angiography which involves placement of a catheter and injection of contract material into a large artery or vein, followed by 2-dimensional visualization with x-rays. Coronary computed tomographic angiography (CCTA) is a minimally invasive radiological technique used to provide images of the heart and surrounding vessels.

CCTA has been suggested as an alternative or useful complementary approach to other non-invasive methods of diagnosing coronary artery disease (CAD). Due to its ability to visualize coronary anatomy, CCTA has been suggested as a strategy to rule out significant CAD among patients at low or intermediate risk of significant disease, thereby giving greater reassurance than other non-invasive methods and potentially reducing the number of patients ultimately sent for invasive coronary angiography (ICA). Potential drawbacks include radiation exposure; duplicative or additional testing; incidental findings; and uncertainty about whether the test results in better health outcomes.

In September 2008, 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, Computed Tomographic Angiography report is 125 pages, identified 8 relevant studies for the Emergency room setting and 34 relevant studies for outpatient, Medicare coverage and 4 expert treatment guidelines. These studies represent the best available information; including a randomized controlled trial for the emergency room setting from which evidence based conclusions were drawn.

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 14th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov in the committee section.

Summary of Committee Findings

The committee found that it had the most complete information: a comprehensive and current evidence report, public comments, and agency utilization information. The committee concluded that the current evidence on Computed Tomographic Angiography demonstrates that there is sufficient evidence a decision about use in an emergency

setting to cover investigation of acute chest pain in an emergency room department or hospital setting for those who are at low-to-intermediate risk of coronary artery disease. The committee concluded that there is not sufficient, reliable evidence developed to make a determination for other coronary CTA uses, including the outpatient setting. For low-to-intermediate risk patients in the Emergency department setting the diagnostic accuracy of the 64-slice as a triage tool was supported by one RCT and several case series. For low-to-intermediate risk outpatients, no RCT or long-term cohort evidence was available. Modeling suggests a lower rate of false negatives than SECHO and SPECT, and a lower rate of false positives than SPECT, but these differences change with underlying prevalence of CAD and involves other trade-offs.

Based on these evidentiary findings, the committee voted: 2 for non-coverage and 7 for coverage with conditions.

- ***Is it effective?***

The committee identified multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology was effective. Summary of committee consideration, discussion, and comments are listed below.

- ✓ *Diagnostic Accuracy – Sensitivity*: the committee agreed as a whole that CCTA has a high level of sensitivity. The technology report sensitivity rate was 98%; which compared favorably to stress echo at 76-94% and SPECT at 88-98%. The indeterminate rates were also lower, with CCTA at 3% versus Stress ECHO at 13% and SPECT at 9%.
- ✓ *Diagnostic Accuracy – Specificity*: the committee agreed equivalent specificity. Some uncertainty about lower prevalence population was shared amongst the committee members. The technology report specificity rate was comparable at 82-88%; compared to stress echo at 88% and SPECT at 77%.
- ✓ *Reduction in invasive CA*: the committee agreed that modeling suggests reduced ICA, but trial evidence data was inconclusive with Rubenstien trial showing reduction and Goldstein shiwoing slight increase, especially when compared to alternative diagnostic tools.
- ✓ *Replace other tests*: most modeled analysis and clinical trials used CCTA in conjunction with other tests. Committee agreed that CCTA wouldn't replace other non-invasive technologies.
- ✓ *Incidental findings*: committee discussed as an issue both we respect to efficacy and safety and concluded that evidence demonstrates incidental findings are not infrequent events. Incidental findings can provide valuable information for diagnosis of previously undetected other diseases but also often leads to uncertainty or further tests to rule out questionable findings. The committee agreed that there is currently no evidence regarding improved patient health outcomes balancing cost and potential harms from further testing and anxiety.
- ✓ *Effect in real world*: Committee discussed several technology assessment key unknowns: whether more disease found will help or harm patients, especially at lower disease levels (clinical relevance is questionable); whether broad dissemination will result in lower test thresholds that may not result in better overall health outcomes but more radiation; and the extent to which CCTA can replace and not add to tests. Additionally, certification of machines and readers

was also discussed; hospitals require JAHCO accreditation and thus have some standards.

- ***Is it safe?***

The committee identified multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology was safe. Summary of committee consideration, discussion, and comments are listed below.

- ✓ *Radiation Exposure* is an important safety outcome to the committee. The committee discussed the technology assessment report findings of an overall cancer risk of .22% for women and .08% for men. Radiation dosage can be reduced through technique and machine type, but it is unknown whether these lowest dosage techniques/machines are used in WA settings. Overall exposure reported at between 2.0-8.0mSV for lower range is equivalent to SPECT; and 12.0 to 14.0 range for higher dose which is equivalent to A-bomb survivor at 2.3 kilometer distance. The committee concluded that there are small but definite risks, within appropriate norms. The radiation risks are high enough to obviate benefit when applied to very low risk patients.
- ✓ *Incidental findings* are also an important safety outcome that the committee discussed as an issue both we respect to efficacy and safety and concluded that evidence demonstrates incidental findings are not infrequent events. Incidental findings can provide valuable information for diagnosis of previously undetected other diseases but also often leads to uncertainty or further tests to rule out questionable findings. The committee agreed that there is currently no evidence regarding improved patient health outcomes balancing cost and potential harms from further testing and anxiety.

- ***Does it provide value (improve health outcome)?***

The committee discussed cost and cost-effectiveness as a whole. This topic generated the least discussion. There are several cost studies for ED and outpatient showing cost savings. The technology assessment report also modeled costs for ED and outpatient showing cost savings using Medicare reimbursement rates. No analysis included costs related to incidental findings or harms. Current state agency reimbursement rates do not correlate with modeled costs (Agency reimbursement for CCTA is higher and for comparators is lower).

- ✓ Committee members were split, with four considering the cost effectiveness currently unproven and five concluding that CCTA is either equivalent or more cost effective in some situations.

Consistency with 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.

- There is no national coverage decision (NCD), however a coverage analysis and memo was issued in 2008 and summarized: there is uncertainty regarding any potential health benefits or patient management alterations from including coronary CTA in the diagnostic workup of patients who may have CAD. No adequately powered study has established that improved health outcomes can be casually attributed to coronary CTA for any well-defined clinical indication, and the body of evidence is of overall limited quality and limited applicability to Medicare patients

with typical co-morbidities in community practice. The primary safety concerns with cardiac CTA are the exposure to radiation and the use of contrast and blocker medications.

- Four expert guidelines were identified that address the use of CCTA for detection of CAD, but not the setting (ED versus outpatient).
    - American Heart Association (2006): evidence supports the use of CCTA for patients with low-to-intermediate stenosis and may obviate the need for ICA.
    - Multi-Society Statement of Appropriateness Criteria for Cardiac Computed Tomography (2006): Appropriateness reviews deemed the use of CCTA for detection of CAD to be appropriate for the following patient populations: chest pain syndrome with intermediate pre-test probability of CAD and uninterpretable EKG or inability to exercise; chest pain and uninterpretable or equivocal stress test results; acute chest pain with intermediate pre-test probability of CAD and no EKG changes and serial enzymes negative; and symptomatic patients requiring evaluation of suspected coronary anomalies.
    - American College of Radiology (2006): CCTA is appropriate for assessment of CAD, although its usefulness for patients with low pre-test probability is unknown. Appropriateness rating of 7 out 9 for the evaluation of chronic chest pain.
    - SCCT/NASCI Consensus Update (2007): CCTA to be appropriate in the following circumstances: (1) to rule out significant coronary stenosis; (2) to evaluate patients with equivocal or discordant results on a stress perfusion or wall motion study; (3) to rule out stenosis in patients with a low pre-test likelihood of CAD and (4) to potentially replace diagnostic catheterization in patients undergoing non-coronary cardiac surgery.

The committee concluded that their decision is consistent with applicable policy and guidelines. There is no national Medicare coverage decision. The decision is consistent with treatment guidelines in that low to intermediate triage will be covered, with the coverage decision being more specific in identifying the place of service. The committee decision is based on all evidence, including public and agency comments and the comprehensive technology assessment report.

Committee Authority

Washington State believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. The HTA gathers and assesses the quality of the latest medical evidence using a scientific research company, takes public input at all stages, and asks a committee of eleven independent health care professionals to review all the information and render a decision at an open meeting. The Washington State Health Technology Clinical Committee (HTCC), an independent committee of 11 health practitioners, determines how selected health technologies are covered by several state agencies. See 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 the evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.