



Health Technology Clinical Committee

Date: November 14, 2008

Time: 8:00 am – 5:00 pm

Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188

Teleconference Bridge: 1-360-923-2997 Access Code: 360-946-1464

Adopted: March 20, 2009

HTCC MINUTES

Members Present: Brian Budenholzer; Michael Myint; Carson Odegard; Richard Phillips; Michelle Simon; Lydia Bartholomew; Jay Klarnet; C. Craig Blackmore; Michael Souter and Louise Kaplan.

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 8:00 a.m. Sufficient members were present to constitute a quorum.
2. **Implantable Infusion Pump Findings and Decision:** Dr. Budenholzer referred members to the draft findings and decision and called for further discussion or objection. The committee agreed to insert a statement under the Committee Decision portion of the Findings and Decision that states: “the committee has received the Implantable Infusion Pump public comments through October 10th at the October 17th and November 14th, 2008 public meeting and have incorporated those comments in finalizing their decision.”
 - *Action:* Six committee members unanimously approved the Implantable Infusion Pump findings and decision document. Two committee members abstained from voting. One committee member wasn’t present at the time the vote was conducted.
 - HTA program staff will edit any typos before finalizing.
3. **Computed Tomographic Angiography Determination:** The HTCC reviewed and considered the Computed Tomographic Angiography for detection of coronary artery disease technology assessment report, information provided by the Administrator, state agencies, and public members; and heard comments from the evidence reviewer, HTA program, agency medical directors, and several public members. 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.



HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Computed Tomographic Angiography	2	0	7

- **Conditions for coverage:** Investigation of acute chest pain in an emergency department or hospital setting who are at low-to-intermediate risk of coronary artery disease. Type of technology to be used is a 64-slice or better. The committee unanimously agreed on these conditions.
- **Action:** The committee chair directed HTA staff to prepare a Findings and Decision document on Coronary Computed Tomographic Angiography reflective of the majority vote for final approval at the next public meeting.

SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

- ✓ The Health Technology Clinical Committee (HTCC) met on November 14, 2008.

Agenda Item: Meeting Open and HTA Program Update

Dr. Brian Budenholzer, HTCC Chair opened the public meeting. Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics, and introductions.

Leah Hole-Curry, HTA Program Director, provided an update on HTA program activities and outcomes.

- ✓ 2009 - Potential Topics will be referred to the Administrator for his consideration, technologies include: Glucose Monitoring, Sleep Apnea Diagnosis and treatment, Calcium Scoring for cardiac disease, Vagal Nerve Stimulation, Elective Cesarean Section, Hip Resurfacing, Osteoarticular Transfer System – Cartilage Surgery (OATS procedure), Bone Growth Stimulators, Massage Therapy for Chronic Head, Neck and Back pain, Transcutaneous Electrical Neural Stimulation (TENS procedure), Essure Permanent Birth Control procedure, and Breast Cancer Tumor Screening.
- ✓ Clinical Committee Recruitment: The HTA program announced that we have an available recruitment on the health technology clinical committee. Daniel Abrahamson resigned from his clinical committee membership at the October 17, 2008 public meeting. The program is working towards filling this open recruitment.
- ✓ Artificial Disc Replacement: the HTA program is in the process of drafting a Findings and Decision on Artificial Disc Replacement. The program will publish post the Findings and Decision to the web and will circulate to the committee members as for comments. The health technology clinical committee will adopt the Findings and Decision at their next public meeting.

Agenda Item: Previous Meeting Business

- ✓ Overview of the draft minutes from the October 17, 2008 public meeting - the minutes are in the process of being drafted by HTA staff, they will then be posted to the web and circulated to committee members for comments. The health technology clinical committee will adopt the October 17th minutes at their next public meeting.
- ✓ Implantable Infusion Pumps Findings and Decision: Dr. Budenholzer referred members to the draft findings and decision and called for further discussion or objection. The committee agreed to insert a statement under the Committee Decision portion of the Findings and Decision that states: “the committee has received the Implantable Infusion Pump public comments through October 10th at the October 17th and November 14th, 2008 public meeting and have incorporated those comments in finalizing their decision.”
- ✓ Committee members commented on draft decision and public comments received:
 - The public comments do not address or challenge the evidence the committee relied upon and the technology report
 - Still has concerns regarding safety issues and discrimination between cancer/non-cancer patients. Public comments reinforced personal view, but majority vote is reasonable

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- the public comments were not based primarily on evidence; committee made a reasonable decision. Chronic pain vs. cancer there is a difference in timing and diagnosis is fatal, and the use for cancer was not before the committee. Comment from widow reinforced safety issues.
- Updated draft decision clarified and laid out decision well. For emerging trials, can re-review if necessary.
- Empathetic emotionally to public comments related to alleviation of pain, but committee made a rational decision based on evidence from a critically appraised report
- Disagree with public comments that statutory burden for committee decision is not met; updated findings reflect rationale and evidence.
- Overriding concern about serious adverse events occurring; case series efficacy evidence does not prove it to be effective are very low quality. Guidelines subsequently provided do not cite new reliable evidence; most cited studies were analyzed and rejected by ECRI;
- An open and transparent process was used, technology assessment included complete and relevant information;
 - *Action:* Six committee members unanimously approved the Implantable Infusion Pump findings and decision document. Two committee members abstained from voting.
 - HTA program staff will edit any typos before finalizing.

Agenda Item: Computed Tomographic Angiography Topic Review

Leah Hole-Curry, HTA Program Director, introduced the primary technology topic to discuss:

- ✓ *Computed Tomographic Angiography for detection of coronary artery disease:* review of the evidence of the safety, efficacy and cost-effectiveness of Computed Tomographic Angiography.

Computed Tomographic Angiography

- ✓ Heart disease is the leading cause of death and disability in 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.
- ✓ 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.
 - Invasive tests include: The “gold” standard is the conventional coronary angiography 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.
- ✓ CCTA involves the use of CT scans and an injected dye to develop computer-aided, 3-dimensional images of the artery.



- ✓ CCTA Potential Benefits: multiple-angle and multiple-plane visualization; improved visualization of soft tissues and adjacent anatomy; and lower degree of invasiveness compared to conventional CA.
- ✓ CCTA Potential Drawbacks: increased radiation exposure; the possibility of incidental findings in adjacent anatomic structures; and the need for further testing (additive rather than replacement test).
- ✓ CMS Decisions and Expert Treatment Guidelines
 - Centers for Medicare and Medicaid Services (2008): no national coverage decision (NCD). Coverage memo conclusions: in summary, 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 comorbidities in community practice. The primary safety concerns with cardiac CTA are the exposure to radiation and the use of contrast and blocker medications.
 - 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 of 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.

Agenda Item: Public Comments

- ✓ Scheduled Public Comments: No scheduled public comments.
- ✓ Open Public Comments: Four individuals provided comments during the open portion (limited to three minute comments) –
 - David Wiley, MedTronic Attorney: gave a statement about MedTronic's disapproval of the August 15th coverage determination on Implantable Infusion Pumps.
 - Dr. Kelley Branch (University of Washington); Dr. William Shuman (University of Washington); and Dr. Edham Ward: provided a statement approving the use of CCTA.

Agenda Item: Computed Tomographic Angiography Topic – Agency Data

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Dr. Malcolm Dejnozka, Uniform Medical Plan Medical Director, presented to the committee the agency utilization and outcomes for Computed Tomographic Angiography.

- ✓ Key agency concerns for prioritization:
 - Efficacy concerns – High: evidence of CCTA sensitivity, specificity, reliability are mixed. Rapid technology evolution/diffusion; what’s the community standard outside the research or “center” experience; interpretation reliability (inter-rater reliability) concerns; and patient selection. Gold standard exists = invasive coronary angiography.
 - Safety concerns – Low: Short-term ~ IV contrast reaction; renal insufficiency; procedure drugs (beta-blockers/nitrates) and dilemma of “incidental findings” which may add potentially harmful tests / procedures. Long-term ~ radiation exposure is significant; especially if a screening tool.
 - Cost concerns – High: economic impact of CAD is greater than \$120 billion (2004). Does CCTA add costs, drive other costs or eliminate need for alternative tests? Half-life of new generation CT propagates market change (variation) and costs.
- ✓ Agency coverage experience (CCTA) – coverage policies vary by agency:
 - L&I: not within scope of services.
 - UMP: deemed “investigational” for most uses, but considered by exception by pre-authorization and medical review.
 - DSHS: covered, requires pre-authorization.
 - The agencies cover alternatives (coverage policies vary by agency): CABG; SPEC (i.e., nuclear medicine stress test); STRESS ECHO and Invasive Coronary Angiography.
- ✓ Data query to CY 2006 and 2007 – claims DATA base query CPT code constraints include: CCTA; ICA; Stress ECHO; and SPECT.
 - Patients may get one, or multiple studies; mixed primary and secondary payer (to Medicare) costs; network / non-network rates; health plan participants (changes in demographics); and site of service.
- ✓ Washington State Agencies Experience:

Invasive Coronary Angiography

Agency	Patients	Average cost (2006/2007)	Total Cost
PEHP*	2,755	\$1,163.20	\$3,204,626.00
DSHS	1,906	\$1,287.83	\$2,454,604.00
TOTAL	4,661	\$1,214.16	\$5,659,220.00
<i>PEHP*</i>	<i>Costs are skewed: UMP was secondary for 1,350 patients covered under Medicare; 1,405 patients UMP primary (average \$1,893.99 paid).</i>		

STRESS ECHO Utilization

Agency	Patients	Average cost (2006/2007)	Total Cost
PEHP*	13,000	\$152.57	\$1,983,345.00

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DSHS	1,566	\$189.92	\$297,421.00
TOTAL	15,687	\$145.39	\$2,280,766.00
<i>PEHP*</i>	<i>Costs are skewed: UMP was secondary for 7,665 patients covered under Medicare; 5,930 patients UMP primary (average \$265.09 paid).</i>		

SPECT Utilization

Agency	Patients	Average cost (2006/2007)	Total Cost
PEHP*	11,434	\$409.49	\$4,682,084.00
DSHS	2,055	\$625.50	\$1,285,400.00
TOTAL	14,599	\$408.76	\$5,967,484.00
<i>PEHP*</i>	<i>Costs are skewed: UMP was secondary for 4,920 patients covered under Medicare; 6,541 patients UMP primary (average \$614.73 paid).</i>		

Coronary CT Angiography Utilization

Agency	Patients	Average cost (2006/2007)	Total Cost
PEHP*	104	\$722.22	\$75,111.00
DSHS	9	\$281.35	\$2,532.00
TOTAL	113	\$687.11	\$77,643.00
<i>PEHP*</i>	<i>Costs are skewed: UMP was secondary for 50 patients covered under Medicare; 54 patients UMP primary (average \$1,186.41 paid).</i>		

Summary of Overall Costs

Agency	Patients	ICA	Stress Echo	SPECT	CCTA
PEHP	27,293	\$3,204,626	\$1,983,345	\$4,682,084	\$75,111
DSHS	5,536	\$2,454,604	\$297,421	\$1,285,400	\$2,535
TOTALS	32,829	\$5,659,230	\$2,280,766	\$5,967,484	\$77,646

Coronary CT Angiography – ICER and Agency Utilization

Procedure	ICER estimates Total ED Costs (Relative Ratio)	Average Agency Costs (Relative Ratio)*
SECHO	\$300 (0.64)	\$190 (0.28)
ICA	\$2,750 (5.90)	\$1,214 (1.77)
SPECT	\$765 (1.64)	\$409 (0.59)
CCTA	\$466 (1.00)	\$687 (1.00)
<i>ICER: "Threshold CCTA cost for cost savings in ED = \$762"</i>		

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* Agency costs (all sites) reflect all variables in setting reimbursement

Only to caution that:
(1) Non-congruence of ED

triage analysis relative to general use in all settings.

(2) Relative impact of reimbursement variables in "real world".

(3) Cannot generalize \$762 "threshold" to use outside the ED (threshold may be significantly lower).

- ✓ Agency Conclusions: Cardiac Imaging for CAD is extensive – imaging options are available and competitive; technology use rapidly disseminating and evolving ("snapshot"); and screening not TEC assessed. Safety and potential harms – less invasive, but subjects' patients to radiation exposure (long-term cancer risk) and dilemma of incidental findings (added studies/interventions). Costs analysis – moderate stenosis reassuring to clinicians/patients or generate an "oculostenotic reflex" (i.e., aggressive tests/treatments); cost advantage seen in the ICER systematic report might be offset by real-world reimbursements and "incidental findings" tests; and cost analytical model shouldn't be generalized outside ED Triage setting.
 - Evidence is most supportive in the ED Triage care setting. Insufficient evidence in other settings.

Agenda Item: Evidence Review Presentation

ICER presented an overview of their evidence report.

- ✓ Scope: CCTA technology 64-slice or better precision, reports between 2005 and present evaluated. CCTA use in emergency department triage of acute chest pain and outpatient evaluation of patients with stable chest pain and low-to-intermediate CAD risk.
- ✓ 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).
 - ICA is typically an inpatient procedure. At the time of the procedure a catheter is inserted into an artery, usually the femoral blood vessel, and contrast dye is injected through the catheter. X-ray images are then captured and displayed on a video screen (a procedure known as fluoroscopy), and can be viewed either as images or in motion picture form. While complications from ICA are relatively infrequent, they can be significant, and include myocardial infarction, cardiac arrhythmia, stroke, hemorrhage, infection, trauma to the artery from hematoma or from the catheter, sudden hypotension, and reaction to the contrast medium.
 - Stress echocardiograms (ECHO) produce images of the heart through the use of sound waves. The test allows for the evaluation of blood flow in different areas of the heart to identify weak or damaged areas of the muscle. This is done through a comparison of images at rest and under cardiac stress induced by exercise or pharmacologic means. Clinically, the test is simple to perform, relatively inexpensive, and easily accessible. However, the image quality is lower in obese patients and those with chronic disease.
 - SPECT imaging involves the use of a tracer radiopharmaceutical to highlight areas of decreased blood flow in the myocardium. Images are captured via a gamma camera, and

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- may be reconstructed to create two or three-dimensional films. The accuracy of SPECT imaging has improved to the point that it is often used for prognostic use in addition to diagnosis. SPECT also involves the use of contrast media and delivers a radiation dose similar in magnitude to that of ICA and CCTA.
- ✓ CCTA is a technique in which a CT scanner is used to acquire multiple simultaneous tomographic sections (“slices”) of the coronary arteries. At the time of this outpatient procedure, an IV is placed into a peripheral vein and a contrast dye is administered for the purposes of visually defining the arteries for the scan. Beta blockers may be given to the patient to slow the heart rate in order to prevent artifacts of heart motion that may affect image quality. The patient is positioned on the CT scanner and a large number of x-ray images are taken from multiple angles and reconstructed using computer software. Multi-detector row CT scanners contain rotating gantries that capture multiple images, or “slices”. A 64-slice CCTA was introduced in 2004 and increased the number of captured images from the previous 16- and 32-slice technology. The 64-slice scanner has rapidly replaced earlier versions and is currently considered to be the community standard for CCTA.
 - In the emergency department, CCTA can be used for the triage of patients experiencing acute chest pain to “rule out” CAD as the underlying cause.
 - In the outpatient setting, CCTA is most often used to evaluate patients with stable, non-emergent symptoms. For such patients CCTA can be used as an initial test or as a method for further evaluation following inconclusive results from another non-invasive functional test.
 - ✓ Compared to other non-invasive diagnostic methods there are also potential disadvantages specific to CCTA, including a small risk of allergic reaction from the use of contrast dye and the risk of renal damage from the dye among patients with pre-existing renal dysfunction. In addition, the increased precision from multi-detector row CT scanners is accompanied by a higher radiation dose to the patient. Lastly, the range of visualization of CCTA extends beyond the heart itself, creating the possibility of identification of “incidental findings” that may or may not be related to the patients’ complaints of chest discomfort.
 - ✓ Description of Included Studies:
 - ED – 8 studies met criteria (N=686); age range = 46 to 58 years; 1 RCT, others single-center case series; and most used clinical diagnosis algorithm for confirmation.
 - Outpatient – 34 studies met criteria (N=3,349); age range = 46 to 69 years; and most used ICA alone or in combination as referent.
 - ✓ Potential Harms – Radiation Exposure: effective dose reported in 17 studies; overall range = 4.6 to 21.4 mSv; lowest rates reported for studies using dose-sparing protocols or dual-source scanners. Six studies reported separate doses for men and women – Men = 7.45 – 15.2 mSv (mean 12.4); Women = 10.24 – 21.4 mSv (mean 14.2).
 - ✓ Evidence review - conclusion interpretation for what is known
 - For asymptomatic: no professional support or evidence for use as asymptomatic screening test
 - For High risk patients: professional guidelines support high-risk patients going directly to invasive catheterization rather than through this test

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- For low-intermediate risk patients in the ED -Diagnostic accuracy of 64-slice as triage tool supported by one RCT and several case series. Modeling suggests that under most assumptions CCTA is cost-saving
 - For low-intermediate risk outpatients - No RCT evidence, no long-term cohort evidence Diagnostic accuracy of 64-slice appears very good compared to ICA and better at identifying occlusion than other non-invasive tests
 - Modeling suggests lower rate of false positives than SECHO and SPECT, and lower rate of false positives than SPECT, but differences change with underlying prevalence of CAD and involves other trade-offs
- ✓ Conclusion interpretation: What we don't know from the evidence
- Does CCTA change clinician threshold for testing?
 - Does CCTA change physician decision-making in the outpatient setting?
 - Does CCTA reduce anxiety or repeat testing?
 - Does CCTA reduce invasive catheterization rates?
 - Are incidental findings a benefit or harm?
 - What is the impact of radiation exposure?
 - Does treatment of CAD identified by CCTA among low-risk populations bring same benefits as treatment of CAD in prior studies?

Agenda Item: HTCC Computed Tomographic Angiography Discussion

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Computed Tomographic Angiography beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

Evidence availability and technology features

The committee finds the following key factors relevant to the coverage decision:

The evidence based technology assessment report indicates that Coronary Artery Disease (CAD) is burdensome and costly; an important and common medical concern. Detecting CAD and appropriately identifying the level of disease is important to select an appropriate treatment and prevent chest pain, heart attack and stroke. There are established non-invasive and invasive tests for detection of CAD. The gold standard comparison is to invasive coronary angiography (ICA); and non-invasive comparators include Stress ECHO and SPECT. The potential benefit of reducing the use of ICA is that it can reduce risks associated with an invasive procedure and reduce usage of associated percutaneous coronary treatment interventions. ICA mortality rates are 1 in 1000 and morbidity from stroke, infection, or bleeding are between .2 and .3%. Potential risks to using CCTA are that the test may be additive rather than a replacement which increases overall risks and costs; radiation exposure; unclear effect on health outcomes of patients and effect of incidental findings.

The committee agreed with the technology assessment findings that there is not current evidence nor professional support for using CCTA in either asymptomatic populations (screening) or very high risk patients who are sent directly to catheterization. The committee further agreed with the



technology assessment distinction by separating discussion of use of CCTA into emergency department use and outpatient use, with a focus on the potential efficacy, safety and costs impacts in populations at low to intermediate risk of CAD.

The evidence based technology assessment report searched peer reviewed medical literature, submitted comments and other sources and identified eight trials, including one randomized controlled trial for emergency department use of CCTA; and 34 trials (no randomized) addressing outpatient usage of CCTA. Finally, the report included four cost studies addressing use of CCTA in ED and outpatient settings.

Key Factors and Health Outcomes Considered – Computed Tomographic Angiography

Efficacy: 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 certification requirements.

Safety: 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 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 finite risks, within appropriate norms. The radiation risks are high enough to obviate benefit when applied to very low risk patients.

- *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.

Cost: The committee discussed cost and cost-effectiveness as a whole. This topic generated the least discussion. There are several cost models 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 model 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.

Medicare Decision and Expert 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.

Agenda Item: Computed Tomographic Angiography Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Computed Tomographic Angiography Votes:

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective	1	6	1	1
Safe	1	7	0	0
Cost-effective	4	1	0	4

Committee Discussion related to ad hoc group. Committee discussed whether an ad hoc group was needed to provide more information to the committee:

- Review of literature is well done; information is present to make decision; there is nothing out there that would likely change view.
- Ad hoc committee would provide more opinion, but committee has good idea of what information is available and what the evidence is.
- We have all the information before us; we just need to make a decision.

HTCC Computed Tomographic Angiography Decision

The HTCC reviewed and considered a comprehensive 2008 HTA Evidence Report on Computed Tomographic Angiography that included and analyzed the relevant and highest quality studies. The committee also reviewed information provided by the Administrator, state agencies, and public members; and heard comments from the evidence reviewer, HTA program, agency medical director, and several public members.

Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Computed Tomographic Angiography	2	0	7

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Committee Discussion related to Expert Treatment Guidelines and Medicare Decision:

- There is no national Medicare coverage decision. The decision is consistent with treatment guidelines in that low to intermediate triage will be covered, although the coverage decision is 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.
- Outcome: The committee chair directed HTA staff to prepare a Findings and Decision document on Computed Tomographic Angiography reflective of the majority vote for final approval at the next public meeting.
- CCTA with Conditions: Investigation of acute chest pain in an emergency room or hospital setting who are at low-to-intermediate risk of CAD.
 - Type of technology to be used is a 64-slice or better.