Washington State Health Care Authority

Health Technology Assessment Program

Health Technology Clinical Committee
November 2008 Meeting

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Washington's Health Technology Assessment Program Background

- **Part of Governor's 2006 Five point health strategy for state to lead by example**
  - **Emphasize evidence-based health care**

    http://www.hca.wa.gov/contf/doc/GovGregoireHealthBrief.pdf

- **Program Purpose: Achieve better health by paying for technologies that work**
  - Better health with better information: investigate what works and maintain a centralized website.
  - Open and transparent process: publish process, criteria, reports, and committee decisions in public meeting.
  - Eliminate Bias: contract for independent evidence report and independent clinical committee.
  - Promote consistency: state agencies rely on a single, scientifically based source.
  - Flexible: review evidence regularly to ensure update information is included.

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Why Now — WA Blue Ribbon Commission

TODAY (2007 Report Findings)**:**

- There are roughly **593,000 Washingtonians without health care** coverage, including 73,000 children.
- The **annual increase in insurance premiums** for small businesses in Washington is **greater than the increase in wages** or gross business income, some years by a factor of five.
- The **state spends an estimated $4.5 billion** on health care, up from $2.7 billion in 2000. Share of the state budget going to health care has increased from 22 percent in 2000 to 28 percent today.
- The United States **spends more** on health care than any other country, but **ranks 28th** in life expectancy and 37th in health system performance.
- ***Approximately 20 to 30 percent of current health expenditures do not improve or extend life. It is also estimated that adult patients receive the recommended care only 55 percent of the time***.

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Why Health Technology — Health Care Context

- **Part of an overall strategy**
- **Medical technology is a primary driver of cost**
  - The development and diffusion of medical technology are primary factors in explaining the persistent difference between health spending and overall economic growth.
  - Some health experts arguing that new medical technology may account for about one-half or more of real long-term spending growth.

    Kaiser Family Foundation, March 2007: **How Changes in Medical Technology Affect Health Care Costs**
- **Medical Technology has quality gaps**
  - Medical technology diffusing without evidence of improving quality Highly correlated with misues, overutilization, underutilization.

    Cathy Schoen, Karen Davis, Sabrina K.H. How, and Stephen C. Schoenbaum, "U.S. Health System Performance: A National Scorecard," *Health Affairs*, Web Exclusive (September 20, 2006): w459

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Washington State Health Care Authority

- Issue: WA citizens pay high cost for health care and receive poorer outcomes
- Common reaction: "Thin the soup or cut the line"
  - Reduce Eligibility, Rates, or Benefits

Vision: Transform WA state from a passive payer to an active purchaser of higher quality, more efficient health care

- Focus: Variability in care is a sentinel of higher cost and worse outcome.

"Better ingredients in the soup make it go farther"

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HTA Goal

Outcome: Pay for What Works

- Coverage decisions:
  - scientifically based
  - use transparent process, and
  - consistent across state health care purchasing agencies
- Formal, systematic process to identify, review, and cover appropriate health care technologies.
  - Is it safe?
  - Is it effective?
  - Does it provide value (improve health outcome)?

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HTA Program – Ongoing Operations

Pay for What Works: Better Information is Better health

- Topic Selection
  - Under Consideration by Administrator
- Coverage Decisions
  - Artificial Disc Replacement Status
- Evidence Reports
  - CCTA completed
  - Cardiac Stent – Multiple Placement underway
- Clinical Committee
  - Recruitment for open
- Implementation
  - Program Metrics and Quality

Washington State Health Care Authority

Coronary Computed Tomography Angiography

Washington State Health Care Authority

Process Overview

1. HCA Administrator Selects Technology

Nominate, Review, Public Input, Prioritize

Semi-annual

2. Vendor Produce Technology Assessment Report

Key Questions and Work Plan, Draft, Comments, Finalize

2-8 Months

3. Clinical Committee makes Coverage Determination

Review report, Public hearing

Meet Quarterly

4. Agencies Implement Decision

Implements within current process unless statutory conflict

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Hierarchy of Evidence

Best: Meta-analysis of large randomized head-to-head trials.

Large, well-designed head-to head randomized controlled clinical trials (RCT):

- Long-term studies, real clinical endpoints
- Well accepted intermediates
- Poorly accepted intermediates

Smaller RCTs, or separate, placebo-controlled trials

Well-designed observational studies, e.g., cohort studies, case-control studies

Safety data without efficacy studies

Case series, anecdotes

Least: Expert opinion, non-evidence-based expert panel reports, and other documents with no direct clinical evidence

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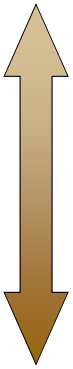
Evidence in Health Care Decision Making



- **Level 3:** *"What would I recommend to the state or nation?"*
  - **Must be based on rigorous assessment of the scientific evidence.**
  - **Affects hundreds of thousands, even millions of people.**
- **Level 2:** *"What would I recommend to my patient/client?"*
  - Influenced by prior experience, but the scientific evidence may play a greater role.
  - Affects possibly hundreds of people.
- **Level 1:** *"Would you have this done for yourself or for someone else in your immediate family?"*
  - Influenced by one's personal experience with the disease and capacity to deal with risk.
  - Affects few people.

Used with Permission from Dr. Mark Helfand, OHSU

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Evidence for use in Policy Decisions

Different Data Sources

- Efficacy
  - How technology functions in "best environments"
    - Randomized trials-distinguish technology from other variables
    - Meta-analysis
- Effectiveness
  - How technology functions in "real world"
    - Population level analyses
    - Large, multicenter, rigorous observational cohorts (consecutive pts/objective observers)
- Safety
  - Variant of effectiveness
    - Population level analyses
    - Case reports/series, FDA reports
- Cost
  - Direct and modeled analysis
    - Administrative/billing data (charge vs cost)
- Context
  - Mix of historic trend, utilization data, beneficiary status, expert opinion

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Heart Disease

- Heart disease is the leading cause of death and disability in US: with 700,00 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 results 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

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Diagnostic Tests

- 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 test includes:

- 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.

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Coronary Computed Tomography Angiography

- CCTA involves the use of CT scans and an injected dye to develop computer-aided, 3-dimensional images of the artery.
- The potential advantages of CCTA include:
  - multiple-angle and multiple-plane visualization
  - improved visualization of soft tissues and adjacent anatomy
  - lower degree of invasiveness compared to conventional CA
- Potential disadvantages of CCTA include:
  - increased radiation exposure
  - the possibility of incidental findings in adjacent anatomic structures
  - the need for further testing (additive rather than replacement test)

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Agency Prioritization

- **Safety concern: tests a large number of patients due to high disease prevalence, so risks should low**
  - **Short term – procedure risk, additional tests, frequency**
  - **Long term - radiation exposure**
- **Efficacy concern:**
  - **Have gold standard test and other alternatives**
  - **Evidence on CCTA sensitivity, specificity, and reliability mixed – diffusion of different technology; less experienced practitioners; and multiple situations of particular concern**
  - **Incidental findings**
- **Cost Concern: testing same population with new technology**
  - **If CCTA is higher or an additional test, worse situation present in that higher cost and worse or no better outcome**

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Medicare Coverage and Clinical Guidelines

Medicare

Date	Outcome
2008	No national coverage decision (NCD). Coverage memo conclusions 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 causally 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 β blocker medications.

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Medicare Coverage and Clinical Guidelines

Medicare

Date	Outcome
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 causally 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 β blocker medications.

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Medicare Coverage and Clinical Guidelines

Organization	Date	Outcome
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 pretest 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.

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CCTA

Questions?

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Washington State Agency Utilization and Costs Review

Health Technology Clinical Committee
Coronary CT Angiography - CCTA

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Key Concerns for Prioritization

- **Efficacy concern: High.**
  - Evidence CCTA sensitivity, specificity, reliability are mixed
    - Rapid technology evolution/diffusion; different generations, imaging techniques
    - What's the community standard outside the research or "center" experience?
    - Interpretation reliability (inter-rater reliability) concerns
    - Patient selection (i.e., What clinical setting (ED, acute, stable, low risk, screening?)
  - Gold Standard exists (invasive coronary angiography)
    - Can it be used to avoid invasive coronary angiography or just another added test?
    - Will it provide any "new" diagnostic/actionable information for the clinician?
- **Safety concern: Low**
  - Short term
    - IV contrast reaction; renal insufficiency; procedure drugs (beta-blockers/nitrates)
    - Dilemma of "Incidental findings" (potentially harmful added tests/procedures)
  - Long term - radiation exposure is significant; especially if a screening tool
- **Cost Concern: High – Economic impact of CAD > $120 B (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

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State Agency Coverage Policy

- **Agency coverage experience (CCTA)***
  - 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***
  - CABG
  - SPEC (i.e., nuclear medicine stress test)
  - STRESS ECHO
  - INVASIVE CORONARY ANGIOGRAPHY

*Coverage policies vary by agency

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Key Concerns for Prioritization

- **Query limited to CY 2006 and 2007**
- **Claims DATA-base Query CPT code Constraints**
  - CCTA
  - ICA
  - Stress ECHO
  - 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)**
- **Site of Service**

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Washington State Agencies Experience

Invasive Coronary Angiography

Utilization			
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
	4,661	$1,214.16	$5,659,220.00
*PEHP**	*Costs are skewed: UMP was secondary for 1,350 patients covered under Medicare; 1,405 patients UMP primary (average $1,893.99 paid)*		

Fiscal Years 2006 and 2007.

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Washington State Agencies Experience

STRESS ECHO

Utilization			
Stress ECHO			
Agency	Patients	Average Cost (2006/2007)	Total Cost
PEHP*	13,000	*$152.57*	$1,983,345.00
DSHS	1,566	$189.92	$297,421.00
	15,687	$145.39	$2,280,766.00
*PEHP**	*Costs are skewed: UMP was secondary for 7,665 patients covered under Medicare; 5,930 patients UMP primary (average $265.09 paid)*		

Fiscal Years 2006 and 2007.

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Washington State Agencies Experience

SPECT

Utilization			
SPECT			
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
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Fiscal Years 2006 and 2007.

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Washington State Agencies Experience

Coronary CT Angiography

Utilization			
Coronary CT Angiography			
Agency	Patients	Average Cost (2006/2007)	Total Cost
PEHP*	104	*$722.22*	$75,111.00
DSHS	9	$281.35	$2,532.00
	113	$687.11	$77,643.00
*PEHP**	*Costs are skewed: UMP paid secondary for 50 patients covered under Medicare; 54 patient UMP primary ($1,186.41 aver. paid)*		

Fiscal Years 2006 and 2007.

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Washington State Agencies Experience

SUMMARY OVERALL COSTS

Agencies 2006/2007	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*

Total costs in cardiac imaging '06&'07 = > $14,017,955 (~ $7.009 M per year)

Fiscal Years 2006 and 2007.

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Agency Coverage Determination (Coronary CT Angiography - CCTA)

Procedure	ICER Estimates Total *ED* Costs (Relative Ratio)	Average Agency Costs (all sites) (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)

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)

ICER: "Threshold CCTA cost for cost savings in ED = $762"

* Agency costs reflect all variables in setting reimbursement

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Agency Conclusions

- **Cardiac Imaging in CAD is extensive**
  - Imaging options are available and competitive
  - Technology use rapidly disseminating and evolving *("snapshot")*
  - What, where and when is CCTA best indicated? (*screening not TEC assessed*)
- **Safety and Potential harms**
  - Less invasive, but subjects patients to:
    - Radiation Exposure (*long-term cancer risk*)
    - 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 ICER report might be offset by real-world reimbursements and "incidental findings" tests
  - 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

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Questions?

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Washington State Health Care Authority

State Agency Cost Information
Coronary Computed Tomography Angiography
November 14, 2008

Health Technology Assessment
676 Woodland Square Loop SE
PO Box 42712
Olympia, WA 98504-2712
Phone 360-923-2742.
www.hta.hca.wa.gov

Background

Disease: Heart disease is the leading cause of death in the United States and is a major cause of disability. Almost 700,000 people, 29% of US deaths, die of heart disease in the U.S. each year. Heart disease is a term that includes several more specific heart conditions. 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 the coronary arteries that results in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries. CAD can affect one or more arteries and be either total or partial narrowing. CAD may be asymptomatic or lead to chest pain (angina), heart attack- myocardial infarction (MI), or death.

Technology: Coronary computed tomography angiography (CCTA) involves the use of CT scans and an injected dye to develop computer-aided, 3-dimensional images of the artery. Multi-slice CT scanners first received FDA approval in 1998, and their use (as well as level of precision) has evolved rapidly since then.

CT angiography in general has proliferated into multiple indications, including head and neck vascular imaging (e.g., for occlusive carotid arterial disease), diagnosis of aortic dissection or thoracic aortic aneurysm, detection of pulmonary embolism, diagnosis of peripheral arterial disease, visualization of the abdominal vascular system (e.g., for abdominal aortic aneurysm), and detection of a variety of cardiac and cerebrovascular congenital abnormalities.

Technology Selection

The focus of this review is on the use of CT angiography for detection of coronary heart disease, given the condition's high prevalence (it is the most common cause of cardiac disease) and importance (it is the leading cause of death in the U.S. for both men and women). CCTA has been suggested as an alternative method to detect and diagnose coronary artery disease.

The key concerns and prioritization information are listed below. Agencies had high concerns that the technology usage in general is rising and this application is diffusing without evidence on test accuracy and important health outcomes. An ultimate health outcome here is whether the test reduces the need for other tests and accurately identifies those patients who need no further treatment, conservative medical care, or surgical intervention (open or catheter based). If used, which situations (e.g. screening, surgical triage, emergency, sub-acute) can the CCTA replace current tests, - either invasive or non-invasive. If this is a replacement test, what cost impact is there and is any cost increase, is there a benefit gained over the replaced test.

Other cardiac related diagnostic tests currently paid for 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

The invasive test 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.

The potential advantages of CCTA include:

- multiple-angle and multiple-plane visualization
- improved visualization of soft tissues and adjacent anatomy
- lower degree of invasiveness compared to conventional CA

Potential disadvantages of CCTA include:

- increased radiation exposure
- the possibility of incidental findings in adjacent anatomic structures
- the need for further testing (additive rather than replacement test)

CCTA Agency prioritization concerns and ranking:

- **Safety concern:** tests a large number of patients due to high disease prevalence, so risks should be very low
  - Short term – procedure risk, additional tests needed, frequency
  - Long term - radiation exposure (especially if used to screen or diagnose large potential group given wide prevalence)
- **Efficacy concern:**
  - Already have gold standard test that is diagnostic and other non-invasive alternatives
  - Evidence on CCTA sensitivity, specificity, and reliability mixed – diffusion of different technology; less experienced practitioners; and multiple situations of particular concern
  - Added tests required if equivocal results or if it does not provide full information for diagnosis
  - Incidental findings – ability to accurately read for significance, potential harm from additional tests and procedures
- **Cost Concern:** testing of same population with new technology
  - If CCTA is higher or an additional test, worse situation present in that higher cost and worse or no better outcome

State Agency Medical Coverage Policy

The technology review is for the use of Coronary Computed Tomography Angiography only, other CT uses are not under review.

The tables below contain the agencies' medical policy.

Current State Agency Medical Policy
Medicaid: CCTA is currently a covered service and requires "preauthorization" by Medicaid clinical utilization review consultants.
Uniform Medical Plan: CCTA is currently a covered service only by Exception, subject to preauthorization review. In most cases it was deemed **"investigational"** by UMP medical consultants. According to UMP's Summary of Benefits, a service or supply is considered experimental or investigational if it is under continued scientific testing and research concerning safety, toxicity, or efficacy and is unsupported by prevailing opinion among medical experts (as expressed in peer-reviewed literature) as safe, effective, and appropriate for use outside the research setting. Providers may request an exception through the UMP medical review staff.
Labor and Industries: This service is not generally within the scope of services covered because heart disease and diagnosis is not typically related to a work place injury. If requested and within scope of services, it would be considered under WAC 296-20-01002 which outlines that in no case shall services which are inappropriate to the accepted decision or which present hazards in excess of the expected medical benefits be considered proper and necessary. Services that are controversial, obsolete, investigational or experimental are presumed to not be proper and necessary. Providers may request an exception through the medical director.

State Agency Utilization

Monitoring cost changes in health expenditures is fundamental to sound policymaking. The agencies use this information to assess the potential impact of new proposals and evaluate current programs. The agencies continually refine what is collected, analyzed and reported in order to provide current, relevant information in a changing health care world. The decisions that the state agencies make have impacts throughout the state. When combined, the participating state agencies are responsible for medical services for over 750,000 people in the state of Washington.

Approximate population affected by HTCC coverage decisions

State Agencies	Affected Population
Uniform Medical Plan	173,000
Labor and Industries	150,000
Medicaid	450,000

To provide context and information about current diagnostic procedures utilization, the agencies have provided population and cost information to provide a state utilization picture. However, utilization and administrative claims information is limited because:

- Billings include secondary payments.
- Limited eligibility.
- Patients are still in the process of receiving medical services.

Invasive Coronary Angiography (2006 and 2007)			
Agency	**Patients**	**Average Cost (2006/2007)**	**Total Cost**
PEHP*	**2,755**	***$1,163.20***	**$3,204,626.00**
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Total Utilization and Costs per Agency for 2006 and 2007

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Total costs in cardiac imaging '06&'07 = > $14,017,955 (~ $7.009 M per year)

Codes for the utilization information were used consistent with the codes used in the independent evidence vendor report analysis. These codes represent a subset of codes that are accepted and billed for services, so likely represent an under count of total agency utilization.

CCTA CPT Codes	
Procedure Code	**Description**
0145T	Computed Tomography, heart, with contrast materials, including noncontrast images, if performed, cardiac gating and 3d image post processing; cardiac structure and morphoology
	Separate Physician fee to read

Invasive Coronary Angiography

CPT Codes for alternatives _ ICA	
Procedure Code	Description
93508	cath placement, angiography)
93510	(Left heart catheterization)
93543	(injection for heart x-rays)
93545	(inject for coronary x-rays)
93555	(imaging, car diac cath

Stress ECHO

CPT Codes for alternatives	
Procedure Code	**Description**
93015	(cardiovascular stress test)
93350	(echo transthoracic)

SPECT

CPT for alternatives	
Procedure Code	**Description**
78465	(heart image (3d), multiple)
78478	(heart wall motion add-on)
78480	(heart function add-on)
93015	(cardiovascular stress test)

Coronary CT Angiography

An Assessment of Comparative Clinical Effectiveness and Comparative Value

Presented to the Washington state Health Care Authority by
Steven D. Pearson, MD, MSc, FRCP
November 14, 2008

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INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Structure of the presentation

- Scope, analytic framework, and key questions
- Systematic Review of published evidence
  - Quality of evidence
  - Findings on patient outcomes, diagnostic accuracy
  - Potential harms
- Comparative Value
  - Decision analytic models
  - Costs, outcomes, and cost-effectiveness
- Key Issues

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Scope

- CCTA technology
  - 64-slice or better precision
  - Reports between 2005 (introduction of 64-slice CCTA) and present evaluated
- CCTA use in
  - Emergency Dept. triage of acute chest pain
  - Outpatient evaluation of patients with stable chest pain and *low-to-intermediate CAD risk*

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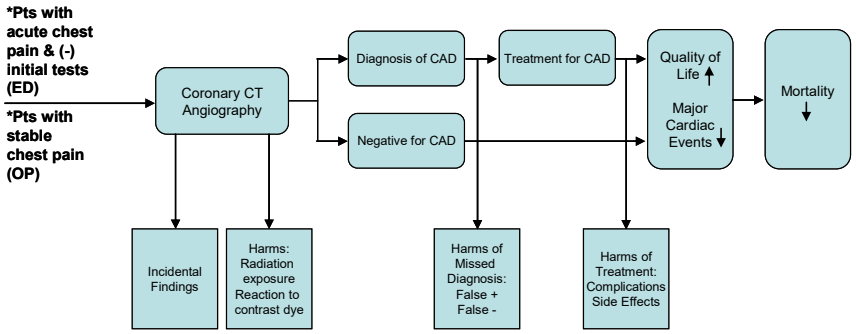
Analytic Framework

Analytic Framework: CCTA in ED and Outpatient Settings



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Key Questions

- What is the impact of CCTA on clinical outcomes?
  - Potential benefits
    - Improved diagnostic accuracy vs. other non-invasive tests
    - Decreased rates of invasive angiography
    - Downstream effects on further tests and preventive treatment
  - Potential harms
    - False positives
    - Increase in testing of low-risk patients
    - Visualization leading to more aggressive treatment
    - Radiation exposure
  - Incidental findings

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Description of Included Studies

- ED
  - 8 studies met criteria (N=686)
  - Age range: 46-58 years
  - 1 RCT, others single-center case series
  - Most used clinical diagnosis algorithm for confirmation
- Outpatient
  - 34 studies met criteria (N=3,349)
  - Age range: 46-69 years
  - Most used ICA alone or in combination as referent

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Description of Included Studies

- Only one multi-center study (diagnostic accuracy)
- Underlying CAD prevalence varied considerably:
  - Mean (SD): 59.0% (20.9%)
  - Range: 18.2%-91.0%
- Few studies account for patients with non-diagnostic segments
  - Patients typically excluded from analyses
  - Our primary meta-analysis conducted using conservative assumption:
    - All patients with non-diagnostic segments (3.2% in our sample) considered false-positives

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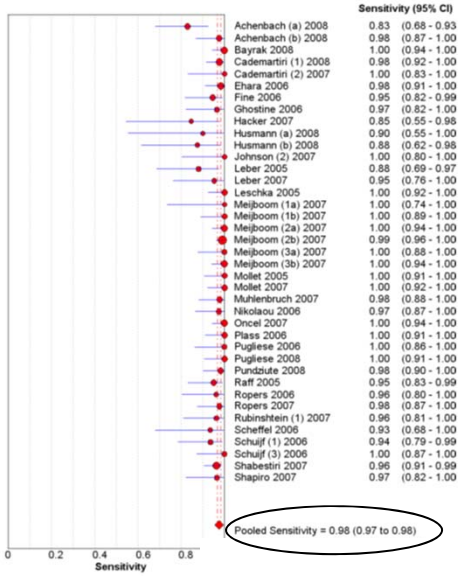
Meta-Analysis Results: Sensitivity



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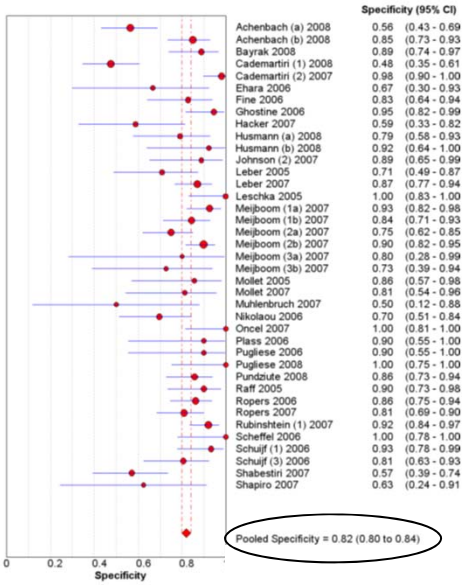
Meta-Analysis Results: Specificity



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Comparative Test Performance

	Sensitivity	Specificity	Indeterminate
CCTA	0.98	0.82-0.87	0.03
Stress-ECHO	0.76 0.94 (for 3-v or LM)	0.88	0.13
SPECT	0.88 0.98 (for 3-v or LM)	0.77	0.09

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ED patient outcome studies

Author	Study Type	N=	Indeterminate Results	Major Findings
Goldstein (2007)	RCT	99	11%	CCTA correctly diagnosed 94 of 99 (95%); no events in CCTA (-) patients
Rubinshtein (2007)	Case series	58	0%	Canceled hospitalization in ~45%; no events in CCTA (-) patients
Gallagher (2007)	Case series	92	8%	Accuracy appeared comparable to SPECT for detection and exclusion of CAD
Hollander (2007)	Case series	54	Not reported	No events recorded; CAD confirmed in 4 of 6 CCTA-positive patients
Savino (2006)	Matched control group	23	Not reported	All moderate/severe stenoses on CCTA confirmed by ICA
Johnson (2007)	Case series	55	0%	CCTA correctly and definitively diagnosed 51 of 55 (93%)

Outpatient outcome study

Author	Study Type	N=	Follow-Up	Indeterminate Results	Major Findings
Pundziute (2007)	Case series	100	Mean: 16 months	4%	1-yr event rate 0% in CCTA (-) patients; 30% in CCTA (+)

Harms: Radiation Exposure

- Effective dose reported in 17 studies
  - Overall range: 4.6 – 21.4 mSv
  - Lowest rates reported for studies using dose-sparing protocols or dual-source scanners
- 6 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)

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Harms: Radiation Exposure

Radiation exposure scenario	Approximate effective dose (mSv)
Chest x ray	0.02
Round-trip flight, New York-Seattle	0.06
Low-dose CT colonography	0.5-2.5
Head CT	2.0
Single-screening mammogram (breast dose)	3.0
Annual background dose caused by natural radiation	3.0/yr
CCTA (lower reported range)	**2.0-8.0**
Invasive coronary angiography	5.0-7.0
Adult abdominal CT scan	10.0
Single photon emission computed tomography (SPECT)	9.0-17.0
CCTA (higher reported range)	**12.0-14.0**
Typical dose to A-bomb survivor at 2.3 km distance from ground zero Hiroshima	13.0
Annual radiation worker annual exposure limit	20.0/yr
Annual exposure on international space station	170/yr

Sources: Brenner FDA 2005; ICER systematic review; Mettler 2008 *Radiology*

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Harms: Radiation Dose

- Recent study* concluded non-negligible lifetime cancer risk attributable to 1 CCTA:
  - 0.22% and 0.08% in women/men aged 60 years
  - Use of tube current modulation estimated to reduce risks by 35%
- Estimates still open to substantial debate:
  - No reliable long-term outcome data
  - Speculation on risk function:
    - ? Linear or non-linear association
    - ? Presence of dose threshold? ? Competing risks

*Einstein 2007 *JAMA*

Benefit/Harm: Incidental Findings

- Reported rate of major findings between 5-20%:
  - Pulmonary nodules most common
  - Aortic aneurysm, pulmonary emboli and infection, hepatic angiomas other examples
- Incidental findings with other CAD diagnostic tests not unheard of:
  - Example: 1.2% in patients receiving SPECT
- Little data or consensus on follow-up requirements or long-term outcome from these findings

*Kirsch 2007 *J Thorac Imag*; Cademartiri 2007 *Radiol Med;* Gedik 2007 *Clin Nuc Med*

Economic Impact: Published studies

- ED
  - 2 resource studies
    - Goldstein RCT: cost-saving
    - University of Penn matched cohort: cost-saving
  - 2 economic models: cost-saving
- Outpatient
  - 2 resource studies from same data set
  - Matched patients with initial CCTA vs. initial SPECT workup
  - Lower CAD-related costs among “CCTA-first” patients

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ICER decision analytic models

- ED triage
  - Low-to-intermediate risk of acute coronary syndrome
- Outpatient evaluation
  - Low-to-intermediate risk with stable chest pain
- Costs and outcomes estimated for
  - diagnostic timeframe only (both settings) and
  - lifetime basis (outpatient model only)
- Incidental findings and radiation risks not modeled

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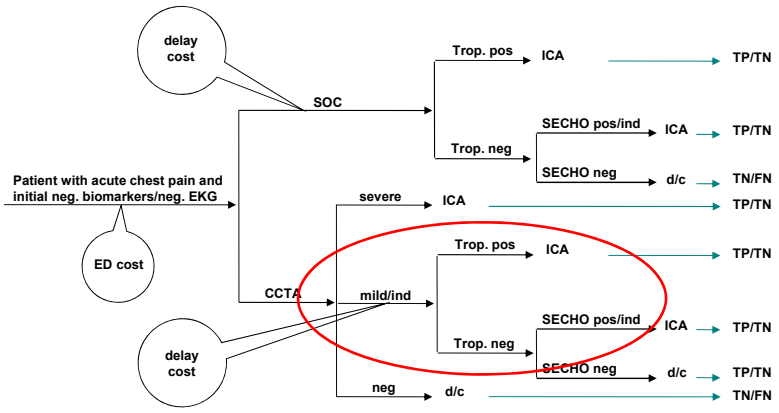
ED Model: Conservative pathway



Notes: severe stenosis: ≥50% stenosis in left main or ≥70% stenosis in any other coronary artery, mild stenosis: 1% to 49% stenosis in left main or 1% to 69% stenosis in any other coronary artery, SOC: standard of care; CCTA: Coronary Computed Tomographic Angiography; Trop.: Troponin; ICA: Invasive Coronary Angiography; SECHO: Stress-echocardigraphy

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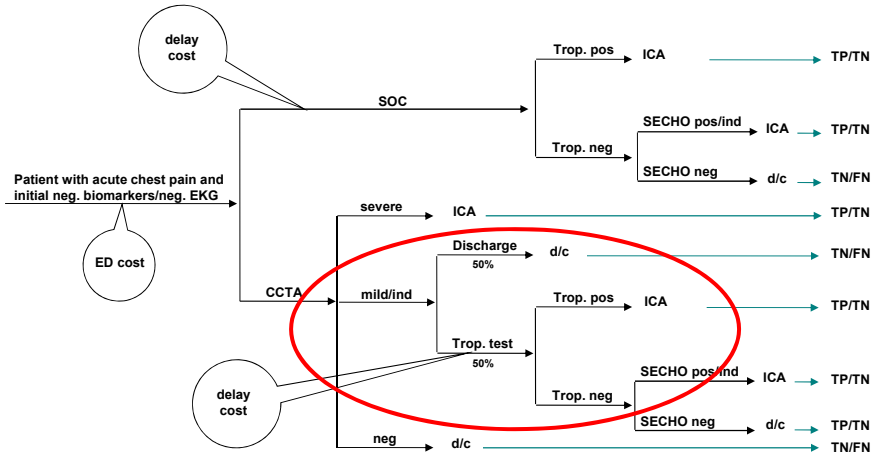
ERG assumptions



Notes: severe stenosis: ≥50% stenosis in left main or ≥70% stenosis in any other coronary artery, mild stenosis: 1% to 49% stenosis in left main or 1% to 69% stenosis in any other coronary artery, SOC: standard of care; CCTA: Coronary Computed Tomographic Angiography; Trop.: Troponin; ICA: Invasive Coronary Angiography; SECHO: Stress-echocardigraphy

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Results for SECHO

ED Model

Outcomes (per 1,000)	Base case SOC	Base case CCTA	ERG assumptions SOC	ERG assumptions CCTA
True positive	218	264	218	256
True negative	731	731	731	731
False negative	51	5	51	13
Referred for ICA	464	380	464	335
ICA negative results	246	116	246	79
ICA related deaths	0.05	0.04	0.05	0.03
Incidental findings w/FU	0	138	0	138
Costs ($ per patient)				
ED/patient	1,152	1,421	1,152	1,393
Delay/patient	443	109	443	62
Cath lab/patient	1,276	1,045	1,276	921
Total/patient	2,871	2,575	2,871	2,376
	cost savings: - $296		cost savings: - $494	

21 ICA: Invasive coronary angiography

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Outpatient Model: Framework

- Target population
  - Underlying CAD prevalence: alternatively 10% and 30%
- Strategies:
  1. Stress-SPECT
  2. Stress-ECHO
  3. CCTA
  4. CCTA followed by stress-SPECT
  5. Stress-SPECT followed by CCTA
  6. CCTA followed by stress-ECHO
  7. Stress-ECHO followed by CCTA

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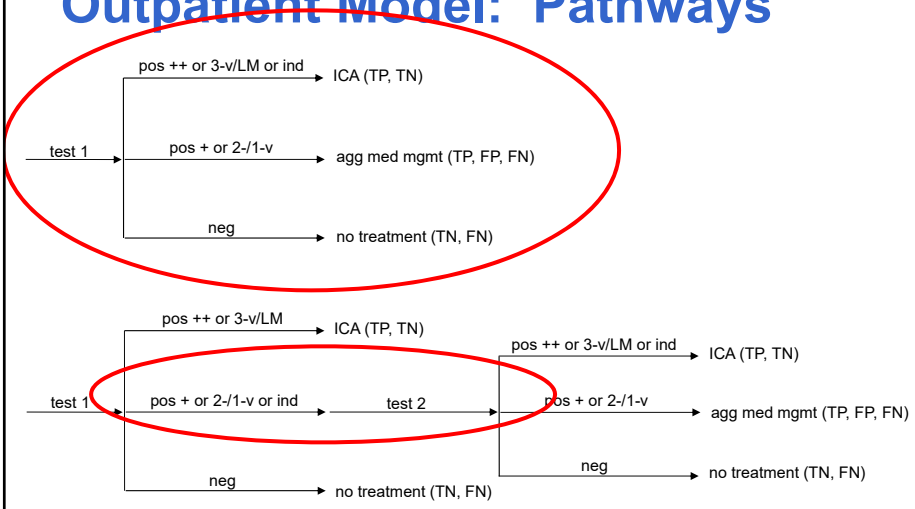
Outpatient Model: Pathways



Notes: pos ++: markedly abnormal test result, pos +: abnormal test result, ind: indeterminate results

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Diagnostic Phase: 30% CAD prevalence

	CCTA	SPECT	SECHO	CCTA-> SPECT	SPECT-> CCTA	CCTA-> SECHO	SECHO-> CCTA
True positive	288	273	251	266	268	245	246
False positive	87	145	71	24	29	12	22
True negative	616	558	632	679	675	691	682
False negative	9	24	46	31	29	52	51
Referred for ICA	108	166	200	106	91	120	87
ICA negative results	22	65	95	9	6	13	5
ICA related deaths	0.11	0.17	0.20	0.11	0.09	0.12	0.09
Exposed to radiation	1,000	1,000	200	1,000	1,000	1,000	437
Incidental findings requiring f/u	138	0	0	138	57	138	48
Total costs per patient [excluding FU]	764	1,221	849	1,004	1,205	891	702

Notes: counts per 1,000 patients, ICA: invasive coronary angiography

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Interpretation: What we know

- No professional support or evidence for use as asymptomatic screening test
- Professional guidelines: high-risk patients directly to invasive cath
- 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

Interpretation: What we don't know

- 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?

ICER Integrated Evidence Rating™: CCTA vs. Standard ED Triage Care

Comparative Clinical Effectiveness	a High	b Reasonable/Comp	c Low
Superior: A	Aa	Ab	Ac
Incremental: B	Ba	Bb	Bc
Comparable: C	CCTA=Ca	Cb	Cc
Unproven/Potential: U/P	Ua	Ub	Uc
Insufficient: I	I	I	I

Comparative Value

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ICER Integrated Evidence Rating™: CCTA vs. Alternative Strategies for Stable Chest Pain

Comparative Clinical Effectiveness	a High	b Reasonable/Comp	c Low
Superior: A	Aa	Ab	Ac
Incremental: B	Ba	Bb	Bc
Comparable: C	Ca	Cb	Cc
Unproven/Potential: U/P	Ua	CCTA=Ub	Uc
Insufficient: I	I	I	I

Comparative Value

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Thank you

Senior Staff	
Daniel A. Ollendorf, MPH, ARM	Chief Review Officer
Alexander Göhler, MD, PhD, MSc, MPH	Lead Decision Scientist
Steven D. Pearson, MD, MSc	President, ICER
Associate Staff	
Michelle Kuba, MPH	Sr. Technology Analyst
Marie Jaeger, B.S.	Asst. Decision Scientist

Appendix

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Lifetime Model: 30% CAD Prevalence

Strategies Ordered by Increasing Effectiveness

Strategy	Effectiveness	Costs
CCTA-ECHO	15.146	7,605
SECHO-CCTA	15.151	7,343
CCTA-SPECT	15.154	7,911
SPECT-CTA	15.157	8,077
SECHO	15.167	7,998
SPECT	15.172	9,051
CCTA	15.183	8,207

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Diagnostic Phase: 10% CAD prevalence

	CCTA	SPECT	SECHO	CCTA-> SPECT	SPECT-> CCTA	CCTA-> SECHO	SECHO-> CCTA
True positive	96	91	82	89	89	81	80
False positive	111	190	94	29	33	14	25
True negative	790	711	807	872	868	887	876
False negative	3	8	17	10	10	18	19
Referred for ICA	56	111	151	41	35	49	32
ICA negative results	28	78	116	11	7	16	5
ICA related deaths	0.06	0.11	0.15	0.04	0.04	0.05	0.03
Exposed to radiation	1,000	1,000	151	1,000	1,000	1,000	303
Incidental findings requiring f/u	138	0	0	138	46	138	37
Total costs per patient [excluding FU]	619	1,071	714	740	1,017	663	514

Notes: counts per 1,000 patients, ICA: invasive coronary angiography

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Outpatient Model: Lifetime Results, 10% CAD Prevalence

Strategies Ordered by Increasing Effectiveness

Strategy	Effectiveness	Costs
SECHO	16.012	4,543
CCTA-ECHO	16.014	3,962
SECHO-CCTA	16.015	3,831
CCTA-SPECT	16.017	4,175
CCTA	16.018	4,645
SPECT-CCTA	16.024	4,450
SPECT	16.030	5,633

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Test Cost Estimates

	Procedure, CPT code (description)	Total cost ($)
SECHO	**93015** (cardiovascular stress test) **93350** (echo transthoracic)	300
ICA	**93508** (cath placement, angiography) **93510** (Left heart catheterization) **93543** (injection for heart x-rays) **93545** (inject for coronary x-rays) **93555** (imaging, cardiac cath)	2,750
SPECT	**78465** (heart image (3d), multiple) **78478** (heart wall motion add-on) **78480** (heart function add-on) **93015** (cardiovascular stress test)	765
CCTA	**0145T** (CT heart w/wo dye funct:$306) Physician fee ($159)	466

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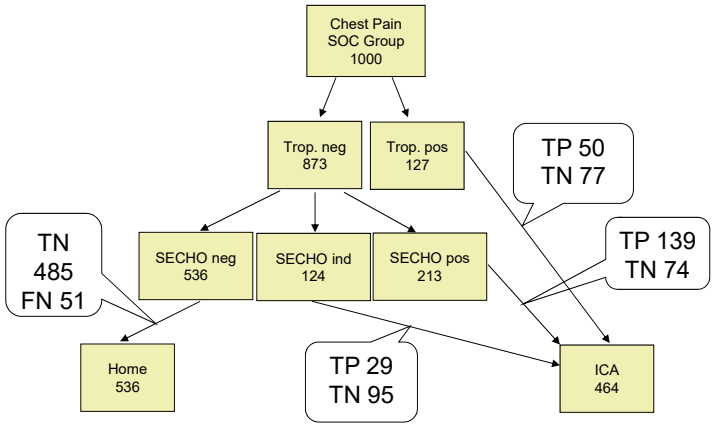
ED Model

ED SOC branch



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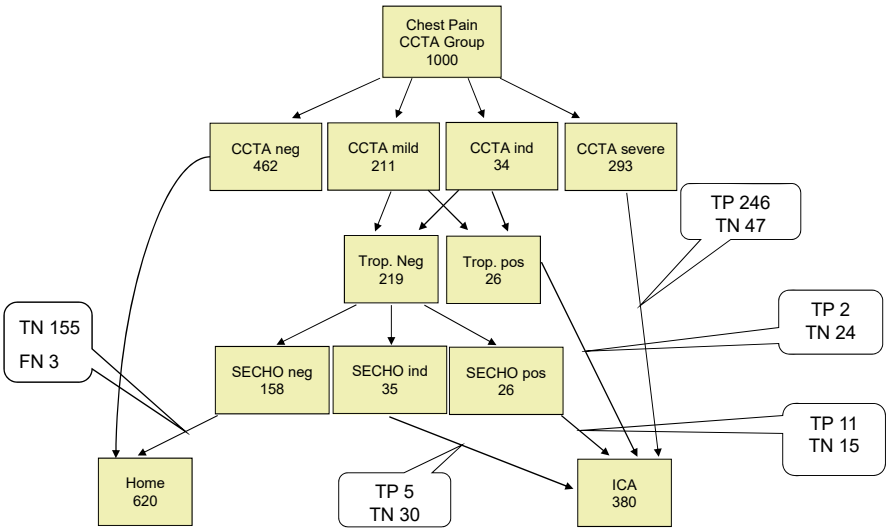
ED Model

ED CCTA branch



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ED Model

Test Cost Estimates

Procedure	Total cost ($) Medicare	Input A*	Input B**
SECHO	300	400	939
ICA	2,750	5,000	5,836
SPECT	765	1,000	1,669
CCTA	466	500	999

Cost for emergency department visit: $890
Costs for delay: $443

Sources: *Rucker ; **Lesser

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ED Model

Results

Costs ($ per patient)	Medicare costs SOC	Medicare costs CCTA + SOC	Input A SOC	Input A CCTA + SOC	Input B SOC	Input B CCTA + SOC
ED/patient	1,152	1,421	1,239	1,477	1,710	2,094
Delay/patient	443	109	443	109	443	109
Cath lab/patient	1,276	1,045	2,320	1,900	2,708	2,218
Total/patient	2,871	2,575	4,002	3,486	4,861	4,421
	cost savings: - $296		cost savings: - $516		cost savings: - $440	

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Results for SPECT

ED Model

Outcomes (per 1,000)	Base case		ERG assumptions	
	SOC	CCTA	SOC	CCTA
True positive	251	261	251	249
True negative	734	734	734	734
False negative	15	5	15	17
Referred for ICA	521	405	521	352
ICA negative results	270	144	270	103
ICA related deaths	0.05	0.04	0.05	0.04
Incidental findings w/FU	0	138	0	138
Costs ($ per patient)				
ED/patient	1,559	1,525	1,559	1,447
Delay/patient	443	112	443	60
Cath lab/patient	1,433	1,114	1,433	968
Total/patient	3,435	2,751	3,435	2,475
	cost savings: - $684		cost savings: - $961	

39 ICA: Invasive coronary angiography

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Outpatient Model: Cost components (30% CAD prevalence)

Strategy	Eff. QALY	Costs ($) total	Non-Invasive tests only	ICA screening only	PCI only	CABG only	Angina Meds only	Meds only
CCTA-SECHO	15.146	7,605	564	327	2,641	2,283	258	1,532
SECHO-CCTA	15.151	7,343	462	240	2,532	2,251	275	1,583
CCTA-SPECT	15.154	7,911	715	289	2,659	2,292	289	1,667
SPECT-CCTA	15.157	8,077	957	248	2,585	2,301	297	1,689
SECHO	15.167	7,998	300	549	2,684	2,251	337	1,877
SPECT	15.172	9,051	765	456	2,722	2,312	445	2,351
CCTA	15.183	8,207	466	298	2,667	2,298	387	2,091

40 Notes: counts per 1,000 patients, ICA: invasive coronary angiography

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HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards. [2]

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.[3]

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	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 causally 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 β blocker medications. However, while public comments and specialty society opinions following the CMS proposed decision to use CED did not dispel the uncertainty of the test's clinical utility, they did strongly favor maintaining the local coverage policies for CTA. In light of this, CMS has decided to make no change in the current NCD. CMS wishes to foster the necessary health outcomes research and believes current guidelines are inadequate to provide appropriate guidance to patients and providers as to the appropriate inclusion of CTA into the diagnostic milieu in the workup of chest pain... We are concerned that providers are using CTA as an additional test added to exercise testing and nuclear imaging rather than thoughtfully considering the appropriate mix of these tests.	Yes	N/A

Note on Medicare Considerations Framework from Decision Memo:
http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=206

We considered the evidence in the hierarchical framework of Fryback and Thornbury (1991) where:

- Level 2 addresses diagnostic accuracy, sensitivity, and specificity of the test;
- Level 3 focuses on whether the information produces change in the physician's diagnostic thinking; Level 4 concerns the effect on the patient management plan and
- Level 5 measures the effect of the diagnostic information on patient outcomes.

Most studies have focused on test characteristics and have not considered health outcomes, such as mortality, morbidity or reduction of invasive angiography. We believe that health outcomes are more important than test characteristics. In evaluating diagnostic tests, Mol and colleagues (2003) reported: "Whether or not patients are better off from undergoing a diagnostic test will depend on how test information is used to guide subsequent decisions on starting, stopping, or modifying treatment. Consequently, the practical value of a diagnostic test can only be assessed by taking into account subsequent health outcomes." When a proven, well established association or pathway is available, intermediate health outcomes may also be considered. For example, if a particular diagnostic test result can be shown to change patient management and other evidence has demonstrated that those patient management changes improve health outcomes, then those separate sources of evidence may be sufficient to demonstrate positive health outcomes from the diagnostic test.

1. CCTA Evidence Questions: Is the evidence sufficient to conclude that cardiac CTA has the ability to diagnose or exclude coronary artery disease as well as invasive coronary angiography? Is the evidence sufficient to conclude that cardiac CTA reduces the need for invasive coronary angiography? Is the evidence sufficient to conclude that the use of cardiac CTA improves health outcomes for patients with acute chest pain who present in the emergency room or other settings?

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
American Heart Association	2006	CCTA has been shown to have a high negative predictive value, and therefore is useful in ruling out CAD. Evidence supports the use of CCTA for patients with low-to-intermediate probability of hemodynamically relevant stenosis and may obviate the need for ICA in these patients.		
Multi-Society Statement of Appropriateness Criteria for Cardiac Computed Tomography	2006	Appropriateness reviews of CCTA and cardiac magnetic resonance imaging deemed the use of CCTA for detection of CAD to be appropriate for the following patient populations: • presenting with chest pain syndrome with intermediate pre-test probability of CAD and uninterpretable EKG or inability to exercise; • presenting with chest pain and uninterpretable or equivocal stress test results; • presenting with 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	An update to their 1995 recommendations determined that CCTA is appropriate for assessment of CAD, although its usefulness for patients with low pretest probability is unknown. On a scale of 9 to indicate appropriateness(9 is most appropriate), CCTA was assigned a rating of 7 for the evaluation of chronic chest pain		
SCCT/NASCI Consensus Update	2007	An update to their 2006 publication found 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.		

NOTE: Several organizations have also developed clinical competence guidelines and/or formal certification processes– these are included in the report.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Mortality - Radiation Exposure	
Morbidity - Contrast reaction -	
-	
Efficacy/Effectiveness Outcomes	**Efficacy/Effectiveness Evidence**
Diagnostic Accuracy: - Sensitivity - Specificity	
Impact on diagnostic and treatment decision making - Reduction in invasive CA - Replace other tests -	
Test characteristics variance by patient subgroup	
Incidental Findings frequency and outcomes	
Cost Outcomes	**Cost Evidence**
Other Factors	**Evidence**
- Equipment type - Reader training	
- Setting (ED vs. Outpatient)	

Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

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

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered. _____ Covered Unconditionally. _____Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?