



**Washington State  
Health Care Authority**

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# **Health Technology Assessment Program**

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**Health Technology Clinical Committee  
November 2009 Meeting**

# 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/conf/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.

- ❑ Overall Issue: WA citizens pay high cost for health care and receive poorer outcomes
- ❑ Government Issue: Public Programs have limited and/or shrinking resources and rising costs and needs.
- ❑ Common reaction: Reduce Eligibility, Rates or Benefits
  - “Thin the soup or cut the line”

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

- ❑ Action: Ensure WA pays for technologies that are proven safe, effective and cost-effective

“Better ingredients in the soup make it go farther”

## 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

### ■ Coverage Decisions

- Cardiac Stents Finalization
- Bone Growth Stimulator Finalization
- Vagal Nerve Stimulator Finalization

### ■ Evidence Reports

- Calcium Scoring (CACs) - Complete
- Hip Resurfacing - Complete
- Electrical Neural Stimulation (ENS) - Complete
- Sleep Apnea Diagnosis and Treatment – AHRQ underway
- Glucose Monitoring – AHRQ underway

### ■ Staffing Changes

- Program Manager Hire – Margaret Dennis
- Clinical Consultant – contract refresh

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# HTA Program – Ongoing Operations

## Pay for What Works: Better Information is Better health

- Topic Selection – 2010 Potential Topics Posted
  1. Kyphoplasty / Sacroplasty / Vertebroplasty
  2. Hyaluronic Acid Injections
  3. Spinal Injections
  4. MRI for Breast Cancer
  5. CT/MRI for abdomen/pelvis
  6. Spinal Cord Stimulation
  7. ABA Therapy for Autism
  8. Routine Ultrasound for Pregnancy
  9. Knee Replacement
  10. Prostate Specific Antigen Testing

## 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

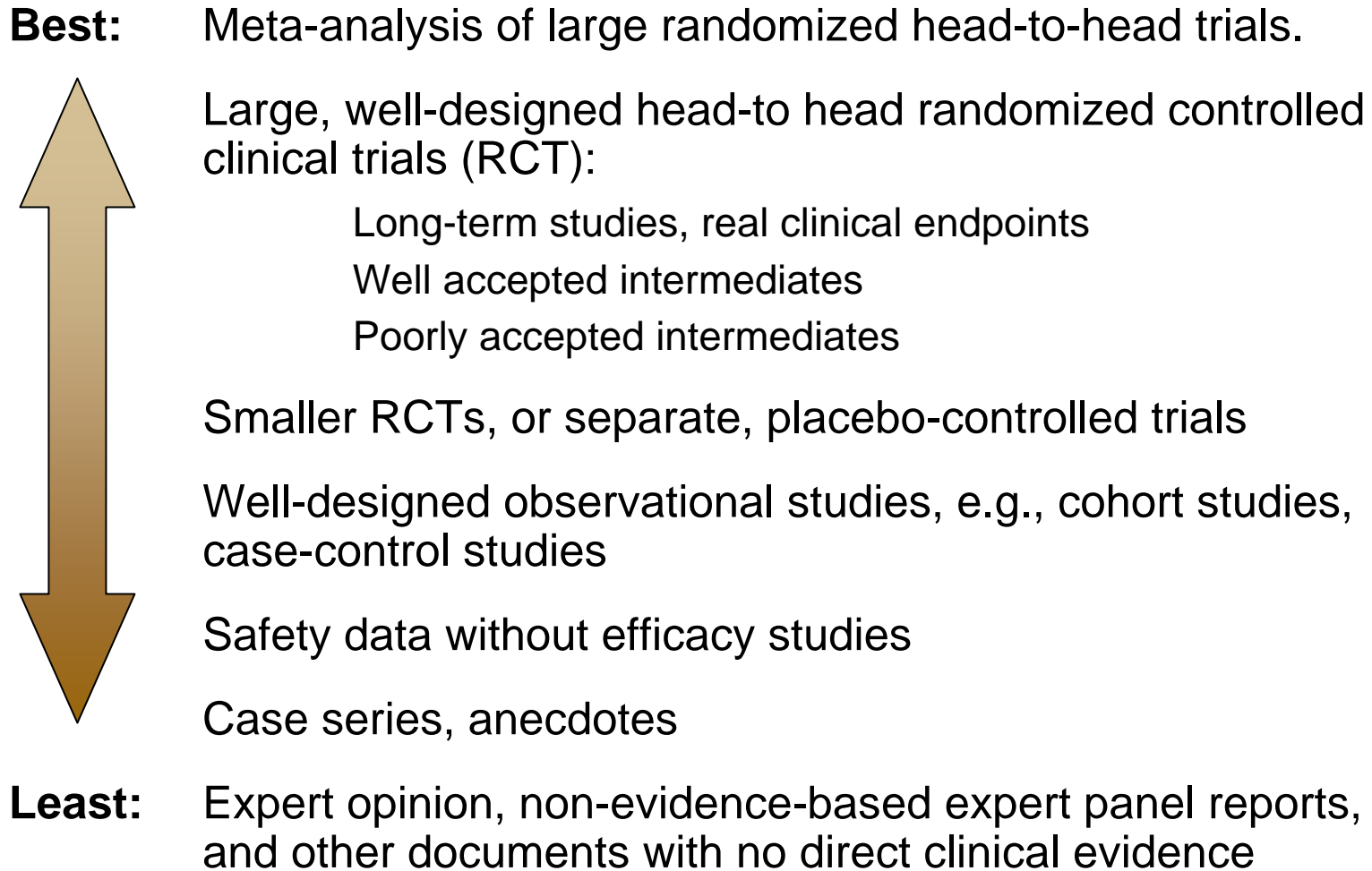


*Meet Quarterly*

## 4. Agencies Implement Decision

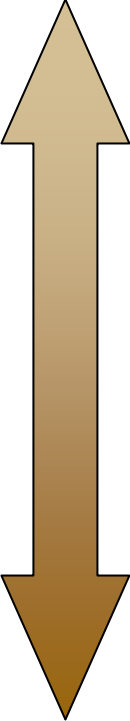
Implements within current process unless statutory conflict

# Hierarchy of Evidence





# Evidence in Health Care Decision Making

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- **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

## 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

# Topic Selection & Decision Process

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# Coronary Artery Calcium Scoring Topic

- Brief Background Relevant to Policy Issues
  - Disease and Diagnosis
  - Treatments
  - Selected Technology
- Agency Prioritization Criteria and Concerns
- Medicare Coverage Decision
- Treatment Guidelines

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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

# 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
- CT angiography with or without calcium scoring uses 3D imaging of the to visualize the heart.

Invasive test includes:

- 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.

# Agency Prioritization

- ❑ Cardiac calcium scoring uses a CT to check for the buildup of calcium in plaque on the coronary arteries. This test identifies and quantifies a marker of coronary disease (plaque), believed to detect earlier stage of CAD.
- **Priority Concerns:**
  - ❑ **Safety–Medium; Efficacy-High; Cost-High**
- **Priority Concern Context CACS**
  - ❑ Concerns that CACS is rapidly diffusing, has a radiation risk (especially cumulative) and is costly, but with little evidence of connection between test result and treatment choices or better health outcomes.

- **Key Question Function**

- Sets parameters for research inquiry and policy decision

- **Key Question Components**

- Legislatively, key questions are centered on a technology's evidence of safety, efficacy, effectiveness, and cost and application in any special population
- Methodologically, questions are refined to include a defined population, intervention, comparator(s), and outcome (PICO)



## ■ CACS Key Question Focus

- When used to diagnose persons with suspected coronary artery disease:
  - What are the test characteristics (PPV, NPV, sensitivity, specificity, reliability)
  - What is the evidence regarding safety?
  - What is the evidence that CACS influences clinical decision making and improves patient outcomes?
  - What is the evidence that CACS may perform differently in special populations?
  - What is the evidence about cost or cost effectiveness?

# Medicare Coverage and Clinical Guidelines

- There is no National Medicare policy on CACS
- Clinical Guidelines:
  - American college of Cardiology Foundation (ACCF/AHA) 2007 expert consensus
    - Lack of evidence to determine if CAC measurement is superior or inferior
      - Additional statements related to specific issues/scenarios
  - American Heart Association (AHA 2006) and 2009 update:
    - Conflicting evidence and divergent opinion on use of CACS resulted in several scenarios where CACS may be considered and others where it should not be used.
  - American College of Radiology 2008 – for assessment of chest pain in low to medium risk patients
    - Appropriateness rating of 3 on scale of 0 to 9, and medium radiation level (1-10msv)

Questions?

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# Hip Resurfacing Topic

- Brief Background Relevant to Policy Issues
  - Disease and Diagnosis
  - Treatments
  - Selected Technology
- Agency Prioritization Criteria and Concerns
- Medicare Coverage Decision
- Treatment Guidelines



# HR Treatment/alternatives

- Conservative management – primarily pain reduction
- Hip Surgery debate in AAOS
  - Total Hip Replacement is a proven, effective technique that results in excellent pain relief and function in most patients for many years.
  - Hip resurfacing has had its ups and downs—with implants that were introduced in the early 1990s, then withdrawn from the market, and reintroduced a decade later.
- “HR is not new...But direct-to-consumer advertising is driving patients to ask for the procedure without really understanding what is involved or even if they are suitable candidates.” 2008 AAOS Annual Meeting

<http://www.aaos.org/news/aaosnow/apr08/clinical4.asp>



**Health Technology Clinical Committee**

**Date:** November 20<sup>th</sup>, 2009

**Time:** 8:00 am – 5:00 pm

**Location:** Marriott Hotel – 3201 South 176<sup>th</sup> Street, Seattle, WA 98188

**Teleconference Bridge:** 1-360-923-2996 **Access Code:** 360-946-1464

**Adopted:**

**HTCC MINUTES**

**Members Present:** Brian Budenholzer; Michael Myint; Carson Odegard; Richard Phillips; C. Craige Blackmore; Louise Kaplan; Megan Morris; Christopher Standaert; Michelle Simon and Michael Souter (arrived late).

**HTCC FORMAL ACTION**

1. **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **October 30<sup>th</sup>, 2009 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, discussion ensued.
  - *Action: Nine committee members approved the October 30th, 2009 meeting minutes. One committee member not present at the time of the vote. Amendment to include Cardiac Stent vote correction.*
3. **Electrical Neural Stimulation draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The Electrical Neural Stimulation findings & decision was approved and adopted by the committee.
  - *Action: Eight committee members approved the Electrical Neural Stimulation findings & decision document. One committee member voted not to approve.*
4. **Cardiac Artery Calcium Scoring (CACS):** The HTCC reviewed and considered the Calcium Scoring technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, and agency medical directors. 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.

<b>HTCC COMMITTEE COVERAGE DETERMINATION VOTE</b>			
	<b>Not covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
<b>Calcium Scoring</b>	<b>10</b>	<b>0</b>	<b>0</b>

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Calcium Scoring reflective of the majority vote.

Draft Version Not Officially adopted – 11/20/2009



5. **Hip Resurfacing:** The HTCC reviewed and considered the Hip Resurfacing technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, the public, and agency medical directors. 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
Hip Resurfacing	0	0	10

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Hip Resurfacing reflective of the majority vote.
- Limitations of Coverage:
  - Total hip resurfacing arthroplasty as medically necessary as an alternative to total hip arthroplasty when all of the following conditions are met:
    1. Diagnosis of osteoarthritis or inflammatory arthritis;
    2. Individual has failed nonsurgical management and is a candidate for total hip arthroplasty; and
    3. The device is FDA approved



## **SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION**

### **Agenda Item: Welcome & Introductions**

- ✓ The Health Technology Clinical Committee (HTCC) met on November 20<sup>th</sup>, 2009.

### **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.

- ✓ Evidence Reports Underway: Glucose Monitoring and Sleep Apnea Diagnosis and Treatment are currently underway with the vendor and the HTA program.
- ✓ Staffing Changes: Margaret Dennis has been hired as the HTA program manager and the contract for program clinical consultant has expired. The program is reviewing alternatives for this role.
- ✓ 2010 Potential Topic Selection: The potential list for 2010 is published on our HTA website. Next steps include the HCA Administrator reviewing all the public comments submitted and making the final selection for 2010. Potential topics include: kyphoplasty / sacroplasty / vertebroplasty; hyaluronic acid injections; spinal injections; MRI for breast cancer; CT / MRI for abdomen / pelvis; spinal cord stimulation; ABA therapy for autism; routine ultrasound for pregnancy; knee replacement and prostate specific antigen testing.

### **Agenda Item: Previous Meeting Business**

October 30<sup>th</sup>, 2009 Meeting Minutes: Chair referred members to the draft minutes and called for a motion and discussion. Minutes were circulated prior to the meeting and posted. One committee member requested that the amendment include a Cardiac Stent vote correction.

- *Action: Nine committee members approved the October 30<sup>th</sup>, 2009 meeting minutes. Amendment to include Cardiac Stent vote correction (found on page 2). One committee member was not present at the time of the vote.*

Electrical Neural Stimulation Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. Staff noted one comment included highlight of several minor/editorial changes; and that the PTWA contacted staff, and could not arrange to be present at the meeting because they had just become aware that the ENS topic included TENS, but would have wanted to provide expertise to the committee. Comments received included: 13 provider, 1 agency medical director, 1 industry (DJO) and 1 society (Physical Therapy of Association Washington – PTWA) comments. Committee reviewed the public comments received and discussed.

- *Action: Eight committee members approved the Electrical Neural Stimulation findings & decision document. One committee member voted not to approve.*



## **Agenda Item: Cardiac Artery Calcium Scoring (CACS) Topic Review**

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Calcium Scoring: review of the evidence of the safety, efficacy and cost-effectiveness of Cardiac Artery Calcium Scoring.

### **Calcium Scoring –**

- ✓ Heart disease is the leading cause of death and disability in US: with 700,000 deaths.
- ✓ The most common heart disease in the United States is coronary artery disease (CAD), which can lead to heart attack.
- ✓ CAD is a narrowing of one or more coronary arteries that result in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries.
- ✓ CAD may be asymptomatic or lead to chest pain (angina), heart attack, myocardial infarction (MI), or death.
- ✓ 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.
    - CT angiography with or without calcium scoring using 3D imaging to visualize the heart.
  - Invasive tests include –
    - The “gold” standard is the conventional coronary angiography (CCA) which involves placement of a catheter and injection of contrast material into a large artery or vein, followed by 2-dimensional visualization with x-rays.
- ✓ Cardiac calcium scoring uses a CT to check for the buildup of calcium in plaque on the coronary arteries. This test identifies and quantifies a marker of coronary disease (plaque), believed to detect earlier state of CAD.
- ✓ Prioritization Criteria Review – priority concern context for CACS: concerns that CACS is rapidly diffusing, has a radiation risk (especially cumulative) and is costly, but with little evidence of connection between test result and treatment choices or better health outcomes.
  - Safety concern: Medium – CT radiation exposure – no system to validate low dose equipment or technique; incidental findings.
  - Efficacy concern: High – test reliability unknown; results of calcium scores not specific and do not correlate with cardiac event risk; low specificity – though very sensitive to the presence of calcium, not all atherosclerosis can be identified; for symptomatic patients – unclear how this added test will change management; and not demonstrated to improve health outcomes.

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- Cost Concern: High – the test is currently additive and not replacement; testing can lead to more intensive and costly treatment; and prevalence of heart disease is very high.
- ✓ Medicare Coverage and Clinical Guidelines:
  - There is no National Medicare policy on CACS
  - CACS Clinical Guidelines – 4 guidelines identified by evidence center:
    - American College of Cardiology Foundation (ACCF / AHA) – 2007 expert consensus. Lack of evidence to determine if CACS measurement is superior or inferior. Additional statement related to specific issues / scenarios.
    - American Heart Association (AHA) 2006, and 2009 update – conflicting evidence and divergent opinion on use of CACS resulted in several scenarios where CACS may be considered and others where it should not be used.
    - American College of Radiology, 2008 – for assessment of chest pain in low to medium risk patients. Appropriateness rating of 3 on scale of 0 to 9, and medium radiation level (1 – 10 msv).

#### **Agenda Item: Public Comments**

The Chair called for public comments.

- ✓ Scheduled Public Comments: No stakeholder requested scheduled time for public comments.
- ✓ Open Public Comments: No individuals signed up or responded to a call for public comments at the meeting.

#### **Agenda Item: Coronary Artery Calcium Scoring (CACS) Topic – Agency Data**

Dr. Nancy Fisher, Health Care Authority, Medical Director, presented to the committee the agency utilization and outcomes for Calcium Scoring.

- ✓ Cardiac calcium scoring uses CT to check for the buildup of calcium in the coronary arteries. Calcium is associated with atherosclerosis and is one marker of CAD. However, coronary calcium is not present in all atherosclerotic plaques and its relevance to risk and treatment is unclear.
- ✓ CACS scans the heart using CT by taking imaging “slices” of the heart. CACS is noninvasive. It offers a potentially less invasive alternative to detect CAD.
- ✓ Radiation exposure through this test is not insignificant.
- ✓ Issues: No clinically significant threshold of amount of calcium established; unclear benefit of diagnosis with calcium score; and test can result in aggressive treatment with unknown health benefit.
- ✓ Current Agency Policies:
  - No specific coverage policy established by UMP, L&I or Medicaid.
    - No utilization data from L&I, as this is not typically related to workplace injury.
    - Newer procedure code is being used and paid.

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- The agencies cover alternative and more accurate tests\* (\* coverage policies vary by agencies) to include: CT Angiography (inpatient only); SPEC (i.e., nuclear medicine stress test); STRESS ECHO and Invasive Coronary Angiography.

Table 1.a. Procedure Code by Year (with payments)

UMP & Medicaid

CPT CODE	2005	2006	2007	2008	Total
0144T (CT, heart, w/o contrast, with eval of coronary calcium)	0	1	3	23	27
0147T (CT angiography of coronary arteries with eval of coronary calcium)	0	8	20	11	39
0149T (Cardiac structure and morphology and CT angiography with eval of coronary calcium)	0	0	13	9	22
<b>Total</b>	<b>0</b>	<b>9</b>	<b>36</b>	<b>43</b>	<b>88</b>
<b>Total Claims Submitted but not paid</b>	<b>0</b>	<b>25</b>	<b>69</b>	<b>83</b>	<b>177</b>

Table 3. Average Payments\* by Procedure by Year

UMP & Medicaid | 2005-2008

CPT Code	2005	2006	2007	2008	Total
0144T	\$0	\$149	\$391	\$132	\$161
0147T	\$0	\$206	\$202	\$418	\$264
0149T	\$0	\$0	\$564	\$516	\$577
<b>Total</b>	<b>\$0</b>	<b>\$199</b>	<b>\$349</b>	<b>\$285</b>	<b>\$302</b>



Summary Average Procedure Costs

Agencies 2006/2007	Patients	ICA	Stress ECHO	SPECT	CCTA
PEHP	27,293	\$1,160.20	\$152.57	\$409.49	\$722.22
DSHS	5,536	\$1,287.83	\$189.92	\$625.50	\$281.35

*Fiscal Years 2006 and 2007.*

### Summary of 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
<b>Totals</b>	<b>32,829</b>	<b>\$5,659,230</b>	<b>\$2,280,766</b>	<b>\$5,967,484</b>	<b>\$77,646</b>

*Fiscal years 2006 and 2007*

### Total Costs in Cardiac Imaging = \$7.00 M per year

- ✓ Agency Recommendations: Insufficient evidence of health benefit and evidence of harm and cost.
  - Cardiac Imaging in CAD is extensive – test and imaging options are available and CACS technology use disseminating without demonstration of benefits.
  - Safety – radiation exposure and dilemma of incidental findings (added studies / interventions).
  - Cost effectiveness / value – unclear how this test improves patient management / outcomes and additive test to increasing cardiac testing expense (theoretical use to rule out or reassure clinicians / patients not shown in real world to reduce further testing and may cause higher use of aggressive tests / treatments).

### Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on Calcium Scoring.

- ✓ Background: calcium deposition in arteries part of atherosclerotic process; CACS is an indirect marker of atherosclerotic burden; correlation of amount with overall plaque on post-mortem;

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detection of calcium is not specific for obstructive lesion; and calcium scores increase with age particularly after 50 years in men and 60 years in women.

- ✓ Literature Search and included studies: 186 potentially relevant studies identified, 55 retained, some with information relevant to multiple key questions. 30 primary accuracy / validity studies identified; 3 reliability studies in symptomatic persons; 2 accuracy studies had reliability information; 7 studies contributed safety information; 10 studies related to decision making and patient outcomes; 5 studies described special populations; 2 full economic analysis and 1 costing study.
- ✓ Meta-analysis of accuracy studies: of 30 accuracy studies, 11 were LoE I or II, 8 were LoE III and 11 were LoE IV.
  - Primary meta-analysis of LoE I/II studies – documentation of independent performance and blinded comparison of CACS and CCA. Study populations included symptomatic patients with typical and atypical chest pain, referral for elective angiography or after positive exercise testing. CAD prevalence ranged from 48.6% to 76.2% based on angiography. CACS thresholds: > 0 (any), ≥ 100 and ≥ 400.
- ✓ Reliability – three studies in symptomatic patients suggest moderate to high inter-observer agreement between raters of calcium scores. Test-retest reliability in symptomatic patients was overall moderate to good across 3 studies.

Author (year)	Study	Measure of reliability	LoE
Broderick (1996) N = 101	Test-retest Inter-rater	Intraclass correlation coefficient 0.90 (test-retest), (N = 17) 0.99 (inter-rater)	II
Möhlenkamp (2001) N = 50	Test-retest	Variability of Agatston score 21.8% (mean), 19.2% (median)	II
Serafin (2009) N = 50	Test-retest	Variability of Agatston score 3.9% (median)	II
Leschka (2008)	Inter-rater	kappa = 0.84	*
Lau (2005)	Inter-rater	Intraclass correlation coefficient = 1.00	*

\* Leschka, Lau were validation studies; specifics on reliability evaluation not provided

- ✓ Potential Harms – Radiation
  - No large-scale epidemiologic studies evaluating CT - associated cancer risk yet published.
  - A recent simulation suggests that a single CACS in asymptomatic persons at: age 40 may increase life-time cancer risk by 9/100,000 for men, 28/100,000 for women; age 55 may increase life-time lung cancer risk by 6/100,000 for men, 14/100,000 for women. Individual risk cannot be quantified.
  - Actual risk associated with low dose radiation is unknown - there are different theories (linear quadratic approach vs. linear, no-threshold hypothesis) and competing risks.
  - Total radiation exposure: To the extent that CACS avoids need for CCA or other tests, the total radiation exposure could be reduced. However current use is additive, and leads to additional testing, with total radiation exposure increased.
- ✓ Potential Harms – Incidental Findings

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- Incidental findings requiring further testing: 7.8% to 10.5% (2 studies); 1.2% required therapeutic intervention (1 study) in symptomatic patients. Potential harms: Additional testing (associated costs, risks), patient anxiety.
- Potential benefits: Early detection (may or may not improve outcomes).
- ✓ Clinical decision making and outcomes:
  - The role of CACS as a diagnostic test and threshold for decision making are not clear. Studies did not include comparison groups (LoE IV). As triage test (low-intermediate risk patients): 5 studies suggest that CACS = 0 or <10 may allow discharge of patients with suspected CAD from ED. Extent to which actual decision for discharge was based on algorithms described and the independent influence of CACS in decision making are unclear. 1 study suggests increased referral for CCA with increasing CACS.
- ✓ Prediction of Future Outcomes: No randomized studies were found. 3 prognostic (LoE III) studies reported CACS predicted future cardiac events; confidence intervals are wide. None evaluated the role of therapies that may have influenced outcomes, definitions of outcomes varied.
- ✓ Special Populations –
  - Sex: Women present - evaluated 10 years later. Specificity of 65% in premenopausal women vs. 42% post-menopausal women (1 study).
  - Age (7 studies): ↑ CACS score with increasing age regardless of gender, presence or absence of significant stenosis. Some suggest that sensitivity and predictive values go up with increasing age, others suggest that the best sensitivity and specificity may be in middle aged patients (40 – 60 years).
- ✓ Economic Impact –
  - Two moderate-quality full economic studies - CACS as a standalone test, triage for CCA. At CAD prevalence up to 70%, CACS may be more cost-effective than CCA, but incremental cost-effectiveness not described. Modeling of false positive and false negative consequences, use of additional testing and impact of incidental findings not explicit. Cost of CCA > CACS, however CCA may still be required as a second test and other tests are available (e.g. functional tests)
  - CAD prevalence: Pre-test CAD likelihood of 30% - 40% had decreased cost from €2345 to €1897 in one study (Dewey), modified societal perspective. Using CACS > 0 in another study (Rumberger), based on short-term direct costs, cost per correct diagnosis were: \$24,703 USD at 10% prevalence; \$6,329 USD at 50% prevalence; and \$4,957 USD at 70% prevalence.
- ✓ Overall Strength of Evidence
  - **Test accuracy – SoE is high**
    - CACS role as diagnostic test in symptomatic patients is unclear; some suggest a triage role with CACS > 0. Highly sensitive, 99%, for identifying obstructive CAD (based on CCA lumen decrease ≥ 50%).
    - Has very low specificity (35%). 5% of persons with negative test would have obstructive CAD on CCA (1 minus negative predictive value).

- **Safety – Radiation exposure - SoE very low**
  - Hypothetical increase in life-time cancer risk based on simulation; true attributable risks cannot be determined.
  - Reduced if CACS results in fewer CCA, however if CACS is an additional test or leads to additional testing, may be increased.
- **Safety – Incidental findings - SoE very low**
  - 7.8%-10.5% require additional testing, 1.2 % needed treatment.
- **Clinical decision making and outcomes**
  - ED triage – SoE is low. Proponents suggest CACS = 0 may allow patient discharge; Decision making does not appear to be explicitly evaluated. Studies of variable quality, no comparison.
  - Other settings SoE is very low (1 study). Referral for CCA increased with higher CACS; explicit evaluation of decision making (or impact) not described.
  - Prediction of outcomes – SoE is low. 3 prognostic studies suggest higher CACS is associated with higher risk of future events, but role of therapeutic interventions not evaluated
- **Special populations**
  - Diabetic populations – SoE is very low. Sensitivity, specificity for any calcium similar to general population. Higher prevalence of CAD; higher % (4%-11%) of missed cases based on 2 moderate quality studies.
  - Male/female – SoE is low. Sensitivity similar; specificity ~ lower in men. Lower CAD prevalence in women vs. men and higher % missed (men) – possibly age related
  - Age – SoE is moderate. Calcium scores increases with age; mixed results.
- **Economic – SoE is very low**
  - Two moderate quality studies suggest that at CAD prevalence of up to 70%, CACS may be more cost-effective than CCA, but incremental cost effectiveness not described. Insufficient evidence for conclusions on long-term cost-utility of CACS compared with CCA alone or in conjunction with other non-invasive tests.
- ✓ Remaining Questions:
  - What is the role of CACS as a diagnostic test? Unclear from the literature; no consensus on thresholds
  - Could CACS be used to triage patients? What threshold? Is the accuracy for CACS > 0 acceptable for decision making? What % of missed cases is acceptable? What false positive rate is acceptable?
  - Does CACS improve upon current triage practices?
  - How does CACS (as diagnostic test) fit in current clinical practice? What is the effect of CACS on total radiation exposure in clinical practice?



- What is the clinical pathway for evaluation of patients with a positive CACS? How is cost-effectiveness impacted?
- Does CACS increase or decrease use of CCA or other tests? How/where does it fit with other non-invasive tests?
- How does it influence decision making for further testing and/or treatment?

### **Agenda Item: HTCC Coronary Artery Calcium Scoring Discussion and Findings**

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

#### **1. Evidence availability and technology features**

- 1.1 The evidence based technology assessment report indicates that coronary artery disease (CAD), also referred to as coronary heart disease (CHD), is the single leading cause of death for both men and women in the United States, affecting more than 16 million Americans, and is the most common form of cardiovascular disease. The underlying cause of CAD is atherosclerosis, a systematic disease process in which plaque builds up within the walls of damaged arteries leading to hardening or narrowing of the vessels and blockage. Common symptoms that occur with CAD are chest pain (angina), arrhythmias, shortness of breath (dyspnea), and in the event of a complete blockage, heart attack. Common risk factors for CAD include smoking, high cholesterol, high blood pressure, insulin resistance or diabetes, obesity, metabolic syndrome, sedentary lifestyle, age and genetics.
- 1.2 Identifying which patients are at risk of major cardiac events is important, but currently difficult. Symptoms of CAD (e.g. chest pain) have poor correlation to risk. Diagnostic testing can be used to help confirm or refute a suspicion of clinically significant CAD. CACS provides anatomical information on the amount of calcium, a marker of CAD in the heart and coronary arteries. CACS role is unclear: it is not currently proposed or likely to be a replacement for conventional coronary angiography (CCA) based on test performance characteristics and lack of consensus about appropriate thresholds. Some literature suggests that it might be used for triaging symptomatic patients and that CACS may reduce the use of conventional coronary angiography.
- 1.3 The evidence based technology assessment report found 396 potentially relevant study citations, with 55 studies included after full review for relevance and redundancy. No randomized controlled trials were found. Five meta-analyses were found, however due to heterogeneity of study design and populations, these were cited for context only.
  - Accuracy (validation) studies = a total of 30 primary studies of accuracy and validity comparing CACS and CCA were identified. Of these, 11 studies were classified as LoE I or II, 8 as LoE III and 11 as LoE IV. Two studies included evaluation of CACS in diabetic populations.
  - Reliability = of 21 studies which explicitly discussed reliability, three studies of moderate quality explicitly stated that symptomatic clinical patients evaluated were identified.
  - Safety = One study which modeled lifetime risk for radiation-induced cancer in asymptomatic persons was found. One systematic review and two studies with patient populations that included symptomatic persons undergoing EBCT for



calcium scoring were identified. Two studies in asymptomatic persons referred for CACS as a screening test and one small study in which it was unclear whether patients were symptomatic or asymptomatic were also identified.

- Clinical decision making and patient outcomes = no studies were identified, all were considered case series.
- Special Populations = two studies provided data comparing CACS with angiography in diabetic patients were identified. Three of the validation studies evaluated tests characteristics based on gender. Seven validation studies provided information on CACS with respect to age.
- Formal economic analysis = two moderate quality full formal economic analyses were identified.

- 1.4 The evidence based technology assessment report identified 4 expert treatment guidelines. No national Medicare policy is available on calcium scoring.
- 1.5 The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, HTA program, and agency medical directors.

## 2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- 2.1 The evidence based technology assessment report indicates that overall strength of evidence regarding safety is very low primarily due to uncertainties regarding the cancer-related risks due to radiation exposure particularly when CACS may lead to additional tests involving radiation. A recent simulation suggests that a single CACS in asymptomatic persons at: age 40 may increase life-time cancer risk by 9/100,000 for men, 28/100,000 for women; age 55 may increase life-time lung cancer risk by 6/100,000 for men, 14/100,000 for women. Individual risk cannot be quantified. The extent to which CACS is an adjunct to CT angiography may increase radiation exposure compared to CACS alone.
- 2.2 Although the overall strength of evidence is very low – data from two studies suggest that 7% - 10% of symptomatic persons will have incidental findings during a CT scan for calcium scoring that require further diagnostic testing and a small percent, 1.2%, will require therapeutic intervention. There may be benefits to early detection and treatment of the small percentage of significant pathology found incidentally; however, there is no evidence from these studies that early detection prompted more effective treatment or enhanced patient outcomes.
- 2.3 The follow-up of less serious findings may create patient anxiety in addition to exposing them to the inconvenience, costs and risks of additional testing.

## 3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- 3.1 The evidence based technology assessment report indicates that the role of coronary artery calcium scoring (CACS) as a diagnostic test is not clear from the literature and there is no consensus on appropriate thresholds for determining a negative versus positive test. It is not

likely to be a replacement for conventional coronary angiography (CCA) based on test performance characteristics. Some literature suggests that it might be used for triaging symptomatic patients and that CACS may reduce the use of conventional coronary angiography.

- 3.2 Accuracy: The evidence based technology assessment report indicated high strength of evidence based on meta-analysis of 8 LoE I / II studies comparing CACS with the reference standard of conventional coronary angiography. Study populations included symptomatic patients with typical and atypical chest pain, referral for elective angiography or after positive exercise testing. CAD prevalence ranged from 48.6% to 76.2% based on angiography. CACS thresholds: > 0 (any),  $\geq 100$  and  $\geq 400$ .
- a. At thresholds of >0, CACS is highly sensitive (99%) for identifying the presence of obstructive CAD (defined as greater than 50% stenosis), however, specificity was low at 35% (meaning 5% of persons with negative tests would have CAD).
  - b. At thresholds of  $\geq 100$  (5 studies) or  $\geq 400$  (3 studies) the sensitivity is lower (85% and 78%, respectively) but specificity is improved (77% and 83%, respectively). However, clinical decisions may not be possible based on CACS when using these thresholds to define a positive test.
- 3.3 Reliability: The evidence based technology assessment report indicates that reliability of CACS (based on Agaston method) is moderate to high, based on 3 level of evidence II graded studies and descriptions in 2 validation studies.

#### 4. Special Populations

- 4.1 Diabetic ~ the evidence based technology report rated overall strength of evidence as low for evidence in symptomatic diabetic patients. It found two moderate quality studies in symptomatic diabetic patients suggest that the sensitivity and specificity of CACS for the detection of any calcium is similar to that for general populations from the meta-analysis of LoE I / II studies but that a higher percent of persons with a negative test would have CAD (11 – 25%).
- 4.2 Gender ~ the evidence based technology report found three moderate quality studies described performance characteristics for men and women separately. Sensitivity for both groups was similar (95% - 100%); but specificity for women was somewhat higher (41%-66%) than men (24%-57%), meaning men would have a higher chance of false-negative tests. The prevalence of CAD was lower in women (36%-47%) compared with men (53%-70%). Women present with CAD at an older age (~ 10 years) than men, which may account for the differences.
- 4.3 Age ~ the evidence based technology report found seven LoE I / II studies exploring the relationship of age with test performance characteristics. The prevalence of CAD and presence of calcium increases with age; however, there were mixed results regarding the extent to which age influenced test performance and the overall strength of evidence was moderate.

#### 5. Clinical Decision Making and Patient Outcomes

- 5.1 The evidence based technology report indicated that the evidence is low that CACS facilitates clinical decision making. While there are a number of studies describing the potential role of CACS as a triage tool for ruling out CAD and identifying those who should have additional testing, none of the studies included a comparison group; therefore, it is difficult to assess the incremental benefit of CACS in clinical decision making.

## 6. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- 1.1 The evidence based technology report found two full economic studies and one costing evaluate CACS as a stand-alone test compared with conventional angiography. In clinical practice, CACS does not appear to function as a stand-alone test. Disease prevalence and CACS score cut-off (and corresponding sensitivity and specificity) appear to influence overall cost-effectiveness. Models did not include evaluation of incidental findings and the influence of false-negative and false-positive tests is not clear. There is insufficient evidence for conclusions on the long-term cost utility of CACS compared with CCA alone or with regard to other non-invasive tests.

### 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.

- 2.1 Centers for Medicare and Medicaid Services – no national Medicare policy.
  - CMS Regional Coverage (Washington and Alaska) – the local regional CMS had determined that there is a lack of evidence of the medical necessity for quantitative evaluation of coronary artery calcium.
- 2.2 Guidelines – a search of the National Guideline Clearinghouse (NGC) returned 4 potential guidelines on Calcium Scoring. The following provides a summary of the guidelines that were most relevant:
  - (1) American College of Cardiology Foundation (ACCF) – Clinical Expert Task Force – lack of evidence from studies comparing CAC measurement to alternative risk assessment techniques for moderate risk patients. No clear evidence is available indicating that additional non-invasive testing in patients with high calcium scores will result in more appropriate selection of treatment over the currently recommended preventative medical therapies. Patients with atypical cardiac symptoms may benefit from CAC testing to help exclude the presence of obstructive CAD.
  - (2) American Heart Association, 2006 – conflicting evidence and/or a divergence of opinion regarding its usefulness was found for the following indications: symptomatic patients with chest pain with equivocal or normal electrocardiograms and negative cardiac enzymes; determining the etiology; symptomatic patients in the setting of ambiguous stress tests; and asymptomatic patients with intermediate risk of CAD. Furthermore, the report stated that despite growing evidence that calcium scores are an independent predictor of CAD studies have not demonstrated improved clinical outcomes as a result of calcium score screening.
  - (3) American Heart Association, 2009 – the following are the minimum requirement which should be met in scanning for coronary artery calcium (CAC): use of an EBCT scanner or a 4-level (or greater) MDCT scanner; cardiac gating; prospective triggering for reducing radiation exposure; a gantry rotation of at least 500 ms; reconstructed slice thickness of 2.5 to 3 mm to minimize radiation in asymptomatic persons (and to provide consistency with established results); early to mid-diastolic gating; and equipment or nuclear material in cardiac imaging should be appropriately utilized to maintain patient doses as low as reasonable achievable but consistent with obtaining the desired medical information.

- (4) American College of Radiology (ACR) Appropriateness Criteria, 2008 – for assessment of chronic chest pain in patients with low to intermediate probability of CAD: CT coronary calcium scoring received a rating of 3 (1 = least appropriate, 9 = most appropriate); a score of zero may be useful in excluding cardiac etiology; and relative radiation level is considered to be medium.
- (5) American College of Cardiology (ACC) and American Heart Association (AHA) for the diagnosis and prognosis of CAD, 2000 – the following are a summary of interpretations and recommendations for cardiac CT scanning and CACS: a negative test (score = 0) makes the presence of atherosclerotic plaque, including unstable or vulnerable plaque, highly unlikely; a negative test is consistent with a low risk of a cardiovascular event in the next two to five years; a positive test (CAC > 0) confirms the presence of a coronary atherosclerotic plaque; the greater the amount of coronary calcium, the greater the atherosclerotic burden in men and women, irrespective of age; and CAC measurement can improve risk prediction in conventional intermediate-risk patients, and CAC plaque scanning should be considered in individuals at intermediate risk for a coronary event for clinical decision-making with regard to refinement of risk assessment.

### **Committee Conclusions**

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

#### **1. Evidence availability and technology features**

The committee concludes that the best available evidence on calcium scoring has been collected and summarized.

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

#### **2. Is it safe?**

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

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

### 3. Is it effective?

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

- 3.1. The committee agreed with the evidence report and found that CACS specificity and reliability are high for CACS, though sensitivity is low and like other tests, accuracy is affected by the disease prevalence. While accuracy and reliability are critical, they are only a first step as to whether a test is effective. The committee also agreed that there is no evidence to establish a clinically important threshold: increase in calcium does indicate disease, but the correlation to severity of stenosis is not established – which is key in a disease that is widely prevalent, where serious events occur in some, but are difficult to predict.
- 3.2. In evaluating effectiveness, the most rigorous question is whether substituting this test, instead of a current diagnostic, results in better treatment and outcomes. In this case, the evidence is insufficient and current clinical practice does not support using this test alone or as a substitute.
- 3.3. The other diagnostic effectiveness key question discussed by the committee is whether there is evidence that using this test as an added tool to current strategy provides a benefit (clinical or cost). The remaining analysis relate to answering this question.
- 3.4. One potential use would be in ER where symptomatic patient at low to intermediate risk - could rule out disease. This use would require CACS of 0 value, so the specificity goes down, and at least a 5% group would still receive a negative test, but would have disease. One small retrospective study looked at 4 month follow up on 100 patients in ED where CACS score was taken, along with other tests and concluded that a score of 0 could permit a discharge. CACS studies did not include any RCT or higher quality observational trials to explicitly test what different clinical or treatment choices are made. Clinical expert noted that usually need a functional test to confirm.
- 3.5. The committee noted national guidelines do not endorse use of Calcium scoring, though some have permissive statements for use of the test.

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

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

### 5. Is it cost-effective?



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

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

**Committee Decision**

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, input from a subject matter expert, agency and state utilization information. The committee concluded that the current evidence on Calcium Scoring demonstrates that there is insufficient evidence to cover the use of Coronary Artery Calcium Scoring (CACS). The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee found that Calcium Scoring would be an additive test that was not supported by sufficient evidence regarding whether it is safe, cost-effective and effectively diagnoses and prevents major cardiac events thus helping patients. Based on these findings, the committee voted 10 to 0 to not cover Calcium Scoring.

**Calcium Scoring Coverage 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.

Calcium Scoring Evidentiary Votes:

Is there sufficient evidence under some or all situations that Calcium Scoring is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
<b>Effective</b>	8	0	2	0
<b>Safe</b>	6	0	4	0
<b>Cost-effective Overall</b>	8	0	2	0

Calcium scoring vote: 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

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	covered	Unconditionally	Under Certain Conditions
Calcium Scoring	10	0	0

Outcome: The committee chair directed HTA staff to prepare a Findings and Decision document on Calcium Scoring reflective of the majority vote for final approval at the next public meeting.

- Calcium Scoring is not covered for symptomatic patients with suspected coronary artery disease.

**Agenda Item: Hip Resurfacing (HR) Topic Review**

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Hip Resurfacing: review of the evidence of the safety, efficacy and cost-effectiveness of Hip Resurfacing.

**Hip Resurfacing –**

- ✓ Conservative management, primarily pain reduction.
- ✓ Hip Surgery debate in American Academy of Orthopaedic Surgeons (AAOS): Total Hip Replacement or Total Hip Arthroscopy (THA) is a proven, effective technique that results in excellent pain relief and function in most patients for many years. Hip resurfacing has had its ups and downs—with implants that were introduced in the early 1990s, then withdrawn from the market, and reintroduced a decade later.
- ✓ Prioritization Criteria Review – priority concern context for HR: Questions remain about the unknown longevity and durability of the procedure; the reported high failure rates; the appropriate patient selection criteria (e.g. age, gender, tried and failed therapies); impact on long term health outcome; higher surgical risks and complications from multiple surgeries and the health system impacts of a surgery designed to delay but not eliminate need for later surgery.
  - Safety concern: Medium – Requirement for re-operation near-term and/or longer-term.
  - Efficacy concern: High – Compared to THA and compared to conservative management.
  - Cost Concern: Medium / High – Demographics suggest high and rising potential demand; considered a delay tactic against anticipated future THA.
- ✓ Medicare Coverage and Clinical Guidelines:
  - There is no National Medicare policy on HR.
    - Potential NCD review list in 2008 - HR may be an alternative to THA replacement that might offer an interim option to patients. Although many patients can expect to outlive the treatment’s effectiveness, HR may have the advantage of preserving enough healthy bone to allow for a future total hip implant. Is the evidence adequate to demonstrate health benefits in the patients who receive the procedure?



- Clinical Guidelines – no clinical guidelines were identified by the evidence center.
  - Search of National Guideline Clearinghouse; additional hand search of AAOS.
  - National Institute for Health and Clinical Excellence (UK) (NICE) (2005) recommended HR for those less than 55 and otherwise needing conventional primary total hip replacement, though acknowledged no RCT comparison and no long term observational data on outcomes.

### **Agenda Item: Public Comments**

The Chair called for public comments.

- ✓ Scheduled Public Comments: Two stakeholders requested scheduled time for public comments.
  - Mike McClure, Smith & Nephew, discussed the cost implications, cost to patients (long term) and a McKenzie article on cost effectiveness.
  - Bert Thomas, Smith & Nephew, discussed how metal-on-metal Hip Resurfacing does indeed work and is the superior bearing. Furthermore, he noted no metal ions and toxicity have been reported.
- ✓ Open Public Comments: Four individuals signed up or responded to a call for public comments at the meeting.
  - Rhonda Fellows, Wright Medical Technology, discussed how their Conserve Plus technology is the 3<sup>rd</sup> metal-on-metal FDA approved device; used within the HTA gold standard; and assists healthcare physician makers.
  - Steve Birnbaum, Wright Medical Technology, noted that revision rates were not going to be different.
  - Larry Pedegana, physician, discussed how he has seen patients who have undergone the procedure and the “choice” of which method should be left to the physician and patient. Furthermore, he indicated that revision rates are comparable between a total hip replacement and hip resurfacing.
  - David Brzusek, Hip Resurfacing patient, noted why he appreciated the hip resurfacing technology over a total hip replacement.

### **Agenda Item: Hip Resurfacing Topic – Agency Data**

Dr. Steve Hammond, Department of Corrections, Medical Director, presented to the committee the agency utilization and outcomes for Hip Resurfacing.

- ✓ Unlike total hip replacement (THA), hip resurfacing does not involve the removal of the femoral head and neck or removal of bone from the femur.
- ✓ Rather, the head, neck and femur bone is preserved in an effort to facilitate future surgery should it be necessary.
- ✓ Hip resurfacing is anatomically and biomechanically more similar to the natural hip joint.
- ✓ Purported benefits include: increased stability, flexibility and range of motion; risk of dislocation; lower and higher activity level possible with less risk than THA; and younger patients needing

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full joint replacement that are expected to out-live the full replacement may benefit from symptom relief and more bone preservation to tolerate a subsequent replacement surgery later.

- ✓ Questions remain about: unknown longevity and durability of the procedure; reported higher failure rates; appropriate patient selection criteria (e.g., age, gender, tried and failed therapies); impact on long term health outcome; and health system impacts of a surgery designed to delay but not eliminate need for later surgery.
- ✓ Current Agency Policies:
  - No Specific coverage policy established by UMP, L&I, or Medicaid.
  - Newer procedure code is being used and paid.

#### Utilization Trends in UMP, L&I and Medicaid

ICD-9 Procedure Codes	2005	2006	2007	2008	Total
00.85 (total hip resurfacing)	0	3	20	22	45
00.86 (resurfacing, femoral head)	0	1	2	2	5
00.87 (resurfacing, acetabulum)	0	0	0	0	0
81.51 (total hip replacement)	432	471	487	614	2004
81.52 (partial hip replacement)	108	100	82	102	392
<b>Total</b>	<b>540</b>	<b>575</b>	<b>591</b>	<b>740</b>	<b>2446</b>

#### Cost Trends in UMP, L&I and Medicaid

ICD-9 Codes	2005	2006	2007	2008	Total
00.85	\$0	\$69,406	\$404,120	\$454,032	\$927,558
00.86	\$0	\$19,991	\$36,344	\$60,457	\$116,792
00.87	\$0	\$0	\$0	\$0	\$0
81.51	\$5,639,160	\$6,378,458	\$6,389,632	\$9,036,877	\$27,444,126
81.52	\$1,264,504	\$940,592	\$957,011	\$1,246,261	\$4,408,368
<b>Total</b>	<b>\$6,903,663</b>	<b>\$7,408,447</b>	<b>\$7,787,107</b>	<b>\$10,797,626</b>	<b>\$32,896,844</b>

\* includes facility, professional and other payments

#### Procedure Cost Trends in UMP, L&I and Medicaid

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ICD-9 Procedure Codes	2005	2006	2007	2008
00.85 (total hip resurfacing)	0	\$23,135	\$22,451	\$20,638
00.86 (resurfacing, femoral head)	0	\$19,991	\$18,172	\$30,229
00.87 (resurfacing, acetabulum)	0	0	0	0
81.51 (total hip replacement)	\$17,902	\$18,650	\$18,361	\$20,037
81.52 (partial hip replacement)	\$20,071	\$17,102	\$21,750	\$21,487

\* includes facility, professional and other payments. Amount paid divided by procedure count.

### Utilization Trends in UMP, L&I and Medicaid

#### Age and Sex by Procedure for UMP, L&I and Medicaid

Age	Gender	00.85	00.86	81.51	81.52	Total
0-19	F	0	0	1	3	4
	M	0	0	0	0	0
20-44	F	3	0	66	9	78
	M	6	1	116	11	134
45-64	F	7	2	579	74	662
	M	27	2	588	53	670
65-74	F	1	0	243	37	281
	M	1	0	193	10	204
75-84	F	0	0	115	64	179
	M	0	0	67	31	98
85+	F	0	0	26	76	102
	M	0	0	8	24	32
Total		45	5	2002	392	2444

- ✓ Agency Conclusions:
  - Agencies only reimburse for FDA approved devices.
  - Should include FDA indications and contraindications.
  - Consider criteria based on population studied: patients with arthritis; failed conservative management and candidate for total hip replacement; and age less than 55.
  - Monitor utilization and cost trends.

#### **Agenda Item: Evidence Review Presentation**

Spectrum Research presented an overview of their evidence report on Hip Resurfacing.

- ✓ Background: Total Hip Arthroplasty (THA) was originally designed for older, relatively inactive patients. Historically, 60 to 80 years of age. The need for hip prostheses in younger patients is increasing. By 2011, more than half of all THA's are estimated to be < 65 years.
- ✓ History of Hip Resurfacing (HR): Initial design (1970-80s) abandoned due to high failure rates caused by metal-on-polyethylene design. New design (1990s) includes high-carbide cobalt chrome metal-on-metal bearings and hybrid fixation (cemented femoral component, uncemented acetabular component).
- ✓ Design of HR versus THA:
  - THA – femoral head removed and replaced with a metal prosthetic ball.
  - HR – surface of the femoral head is removed and replaced with a metal cap inserted into the femoral shaft.
  - Both HR and THA replace the acetabulum with a metal cup.
- ✓ Theoretical advantages of HR versus THA -- reduction in stress-shielding as more normal femoral loads are maintained; improved function due to preservation of femoral head; lower morbidity at time of revision surgery than that which occurs in THA patients; lower risk of dislocation; better replication of normal anatomy; and greater range of motion.
- ✓ Indication for HR (FDA) -- Adults who may not be suitable for THA due to increased risk of ipsilateral hip joint revision as a result of their younger age and/or increased activity level, and who have pain due to: Non-inflammatory degenerative arthritis (e.g., osteoarthritis, traumatic arthritis, avascular necrosis with < 50% involvement of the femoral head, or developmental hip dysplasia), or inflammatory arthritis (e.g., rheumatoid arthritis).
- ✓ Contraindications for HR (FDA) – Infection or sepsis; skeletal immaturity; conditions that could compromise implant stability or postoperative recovery (i.e., vascular insufficiency, muscular atrophy, neuromuscular disease); inadequate bone stock to support the device, including: severe osteopenia or osteoporosis, severe avascular necrosis (> 50% of the femoral head), and multiple femoral neck cysts (< 1 cm in diameter); females of child-bearing age; BMI > 35; known or suspected metal sensitivity; moderate or severe renal insufficiency; and immunosuppression (i.e., AIDS, those receiving high doses of corticosteroids).
- ✓ Inclusion Criteria ~ Study Design:
  - Key Question 1 – RCTs and comparative studies with concurrent controls.
  - Key Questions 2 & 3 – RCTs and comparative studies with concurrent controls, registry studies, case-series with > 5 years follow-up.
  - Key Question 4 – economic analyses and cost data from other HTAs or other published articles.
- ✓ Inclusion Criteria ~ Study parameters for key questions 1 – 3:
  - Population: primary HR for arthritis, developmental dysplasia, or osteonecrosis.
  - Intervention: modern commercially available hybrid HR device. FDA-approved and un-approved devices with at least one year of follow-u data available in peer-reviewed journals were included.
  - Comparator: primary THA.
- ✓ Generalizability: RCTs –

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- Patients: Average age 49 – 52 years, 60 – 89% males. Most patients had only one hip treated, but some had both (as reported by two studies).
- Surgical indication (reported by two studies): osteoarthritis (76 – 77%); developmental dysplasia (6-8%); osteonecrosis (2-6%) and other.
- ✓ Cohort Studies – 1 prospective cohort study; 8 retrospective cohort studies; N (range) = 42 – 603 patients; LoE III (all); and
  - Follow-up: Short term (> 5 years) = 8 studies; mid-term (5 – 10 years) = 1 study (5.9 years); and long-term (10+ years) = none.
- ✓ Registry Studies Comparing HR with THA: 3 international registry studies –
  - Australian Joint Replacement Registry (2008) – data from about 292 hospitals; THA: 125,004; HR: 10,623; primary outcome = time to revision.
  - National Joint Registry for England and Wales (2008) – data from National Health Service and private providers; THA = 152,337; HR = 14,235; primary outcome = time to revision.
  - Swedish Hip Arthroplasty Register (2007) – data from 79 public and private hospitals; THA = 283,089; HR = 1041; primary outcome = survival, complications.
- ✓ Results:
  - Short Term Efficacy: from 3 RCTs, HR is similar to THA with respect to functional, QoL and activity outcomes. Strength of evidence = moderate.
  - Short Term Effectiveness: from 9 cohort studies, HR is similar to THA with respect to functional and QoL outcomes; activity scores slightly higher in HR patients. Strength of evidence = Low.
  - Mid Term Efficacy / Effectiveness: No evidence for Efficacy. 1 cohort study for effectiveness, HR patients have higher QoL scores after 6 years follow-up and similar functional scores. Strength of evidence = Very Low.
  - Short Term Safety: short term revision rates are slightly higher in patients treated with HR compared with THA in the majority of studies. Strength of evidence = moderate.
  - Mid Term Safety: from 1 registry study, cumulative revision rates are higher after 7 years among those with HR vs. THA. Strength of evidence = Low.
  - Complications – complication rates are low following HR in the short and mid-term. Strength of evidence = Low.
- ✓ Metal ion safety concerns ~ Strength of Evidence = Very Low: Elevated Co and Cr serum levels are likely to occur following metal-on-metal HR and THA; concerns over safety of and risks associated with prolonged exposure to metal ions; no association has been found with current lengths of follow-up between metal-on-metal prostheses and cancer or metabolic disorders; and metal ions are known to cross the placenta, thus metal-on-metal prostheses are not indicated for females of child-bearing age.
- ✓ Differential Effectiveness:
  - HR in dysplasia vs. other arthritic conditions: from 1 registry study and one small prognostic study, short-term revision rates are higher following HR for patients with

- dysplasia vs. other arthritic conditions. Registry study: 12% vs. 3% (5-year cumulative rate). Prognostic study: 5.2% vs. 0%. Strength of evidence = Low.
- HR in osteonecrosis (AVN) vs. other arthritic conditions: from 1 registry study and 1 small prognostic study, short-term revision rates are higher following HR for patients with osteonecrosis vs. other arthritic conditions (6% vs. 3%). Strength of evidence = Low.
  - HR in females vs. males: from 3 registry studies, short-term revision rates are higher for females than males (hazard ratio range: 1.57 – 2.5). Difference in rates between sexes was not significant when controlling for femoral component size; smaller femoral heads are correlated with higher failure rates. Strength of evidence = Moderate.
  - Obesity: from two low quality studies, 1 reported lower revision risk and 1 reported higher revision risk with increasing obesity. Strength of evidence = Very Low.
- ✓ Economic Conclusions: From two published studies and one HTA – limited evidence is available on the cost-effectiveness of HR versus THA or waiting followed by THA in patients under the age of 65. More accurate revision rates following HR are needed to fully understand whether HR is cost-effective. Strength of evidence = Very Low.
- ✓ HTA Report Interpretation: What We Know –
- The short-term (< 5 years) efficacy/effectiveness of HR is similar to THA *although there is low evidence that HR may lead to improved activity scores* (moderate/low evidence);
  - Short- and mid-term revision rates are higher following HR compared to THA (moderate and low evidence);
  - Short- and mid-term complication rates (other than revision) are relatively low following HR (low evidence);
  - Patients with dysplasia or osteonecrosis have a higher revision rate than those with other arthritic conditions following HR (low evidence); and
  - Females may have a higher revision rate following HR than males (moderate evidence).
- ✓ HTA Report Interpretation: What we Don't Know –
- The mid- or long-term efficacy/effectiveness of HR (very low to no evidence);
  - Long-term revision rates following HR compared to THA (no evidence);
  - Whether obese patients have a higher risk of revision than patients with a BMI < 30 following HR (very low evidence); and
  - The economic implications of HR; updated revision rates are needed for better prediction models (very low evidence).




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**Agenda Item: HTCC Hip Resurfacing Discussion and Findings**

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

**1. Evidence availability and technology features**

- 1.1 The evidence based technology assessment report found 144 potentially relevant study citations, with 28 studies included after full review for relevance and redundancy (published in 2006 to 2009 timeframe). Four randomized controlled trials (Level of Evidence (LOE) II) and nine cohort studies (Level of Evidence III) comparing efficacy between THA and HR were found, with 11 additional lower quality studies (LOE II, III, and IV) around safety included.
  - Efficacy/Effectiveness: 3 LOE II RCTs conducted using a non-FDA approved device, totaling approximately 350 patients, with a mean age of 50 yrs and majority male (60% to 85%), where reported osteoarthritis was the primary indication (~75%); small sample size; differences in baseline; methods limitation (independent assessment, blinding, intention to treat) and funding sources contributed to the LOE II grading. One prospective and 10 retrospective cohort studies were also included with a LOE III grading, with sample sizes ranging from 42 to 603 (1598 total patients), with similar mean ages and gender demographics to RCT, most using FDA approved devices, with osteoarthritis a predominant diagnosis.
  - Safety: Additional registry data from Australia, Wales and Sweden are included with information primarily on time to first revision, but also including short term complications and 10 year (device) survival rates.
  - Cost: Two previous HTAs and two articles were included for economic implications.
- 1.2 The evidence based technology assessment report found no clinical guidelines listed in the National Guideline Clearinghouse for hip resurfacing procedures, and Medicare does not have a national coverage decision. An additional hand search of the American Academy of Orthopaedic Surgeon website did not identify any guidelines. NICE (UK) has a guidance that concluded that recommends Metal on Metal (MOM) HR as one option for people with advanced hip disease who would otherwise outlive a Total Hip Arthroplasty (THA), although there is an acknowledge of a lack of quality RCT data and long term outcome data.
- 2.3 The evidence based technology assessment report indicates that severe degenerative hip diseases, most prevalent in older patients, age 60 to 80, have been effectively treated with surgical joint replacement, or THA. Joint replacement has been increasingly used in younger (under 65) patients. A concern with younger patients receiving THA is that they may outlive the artificial joint, especially as younger patients tend to be more active. The evidence based technology assessment report indicates that Hip Resurfacing (HR) is proposed as a bone conserving alternative to the conventional THA after optimal medical therapy fails. Unlike THA, hip resurfacing does not involve the removal of the femoral head and neck or removal of bone from the femur. Rather, the head, neck and femur bone is preserved in an effort to facilitate future surgery should it be necessary and to enable the patient to take advantage of newer technology or treatment in the future. Hip Resurfacing is anatomically and biomechanically more similar to the natural hip joint.
  - a) Proposed benefits of hip resurfacing include: increased stability, flexibility and range of motion. Younger patients needing full joint replacement that are expected to outlive the full replacement may benefit from symptom relief and increased bone preservation to tolerate a subsequent replacement surgery later. With hip resurfacing, the risk of dislocation is lower and the possible activity level is higher with less risk than THA. Questions remain about the unknown longevity and durability of the procedure; the

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magnitude of the reported failure rates; the appropriate patient selection criteria (e.g., age, gender, tried and failed therapies); impact on long term health outcomes; additional surgical risks and complications from multiple surgeries, and the health system impacts of a surgery designed to delay but not eliminate the need for later surgery.

## 2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- 2.1 The evidence based technology assessment report indicates short-term (< 5 years) safety data were reported by three national registry studies, two RCTs, and eight cohort studies (one prospective and seven retrospective), while mid-term (5 – 10 years) safety data was reported by one retrospective cohort study, six case-series. No long-term safety data were available.
- 2.2 The primary safety outcome is the revision rate for HR as compared with THA, and overall the evidence based technology assessment report indicates that there is moderate evidence that short term (under 5 years) revision rates are higher for HR; and low evidence that mid- term (5 to 10 years) revision rates are higher for HR (from one registry).
  - Revision (short-term): Data from three national registry studies suggest that revision rates are statistically higher in those receiving HR (3.1%; 5.43%, 2.8%) compared with THA range of (2.5%; 2.04%; and .7%) after three years of follow-up. Comparative studies reported short term revision rates for HR of 0%-7.8% and for THA of 0% to 4.3%.
  - Revision (mid-term): The Australian National Joint Replacement Registry has 7-year follow-up data for 10,623 HRs. A comparison of time to revision revealed a significantly higher revision rate for HR compared with conventional THA with cumulative rate for HR of 4.6% and for THA of 3.4%
  - One small retrospective cohort study with 5.9-year follow-up reported similar revision rates in hips treated with THA (7.8% planned) compared to those who underwent hip resurfacing (7.1%). Revision rates for resurfaced hips ranged from 0% to 7.7% as reported by six case-series.
- 2.3 The evidence based technology assessment reported risks of other complications in the short-term for HR are generally low, except for heterotopic ossification. Revision risks include: femoral neck fractures; avascular necrosis; femoral component loosening; acetabular component loosening; acetabular component migration; and/or heterotopic ossification.
- 2.4 The evidence based technology assessment reported on a Metal ion safety concern: patients with metal-on-metal HR or THA are likely to experience elevated metal serum levels (Co and Cr). Concerns have been raised regarding the safety of and risks associated with prolonged exposure to metal ions, and whether such exposure may increase the risk of cancers or metabolic disorders.
- 2.5 The evidence based technology assessment reported a number of studies that identified that the rate of major complications (including femoral neck fracture and revisions) decrease as surgeons gain experience performing HR. The studies suggested that experience is associated with improved surgical technique and patient selection.

## 3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- 3.1 Efficacy: The evidence based technology assessment report indicates there is moderate evidence from three small randomized controlled trials that HR is similar to THA with respect to short-term (1 year) functional, quality of life and activity outcomes. There is no data available to assess efficacy beyond one-year follow-up and these studies used a non-FDA approved HR device.
- 3.2 The evidence based technology assessment report indicates that there were eight cohort studies (one prospective and seven retrospective) that provided short-term (< 5 years) and one retrospective cohort study that reported mid-term (5.9 years) data regarding the effectiveness of HR compared with THA and was rated at an overall strength of evidence of low (short term) and very low (mid term).
  - No significant difference was reported on patient reported outcomes, activity scores; clinician based outcomes and pain (e.g. as identified in Harris hip scores; Oxford scores or pain scores) in the short-term data.
  - Activity scores for post-operative time period were reported in three cohort studies as significantly higher for HR patients (3-6 vs. 6-8); and two studies reported short term patient activity as higher in the HR patients (5-7 vs. 10-11).
- 3.3 There is very low evidence from one cohort study to suggest that at an average of 5.9 years follow-up, patients treated with HR may have better quality of life and activity outcomes scores, but similar functional scores, compared with those treated with THA.

#### 4. Special Populations

- 4.1 The evidence based technology reported low evidence to suggest that short-term revision rates are twice as high in patients who receive HR for a primary diagnosis of dysplasia compared with patients of primary osteoarthritis. The 5-year cumulative revision percent for dysplasia is four times greater in those receiving HR compared with THA (12% vs. 3%) in one registry study. One small prognostic study supported this data, with 5.2% revision rates in dysplasia patients compared with 0% revision rates in osteoarthritic patients.
- 4.2 There is low evidence to suggest that short-term revision rates are slightly higher in patients who receive HR for a primary diagnosis of osteonecrosis (AVN) compared with patients of primary osteoarthritis. The 5-year cumulative revision percent for dysplasia is two times greater in those receiving HR compared with THA (6% vs. 3%) in one registry study and rates are the same in one small prognostic study.
- 4.3 Gender: There is moderate evidence from three registries that 3- and 5-year revision rates are higher in females than in males.
- 4.4 Obesity: Two low quality studies evaluated the effect of obesity on HR with conflicting results. One reported lower revision rates with increasing obesity, and one reported higher.
- 4.5 SARI Index: Two low quality studies evaluated the effect of the SARI index on HR. Both suggest a SARI score  $\geq 3$  preoperatively results in an increased risk of early complications and revision.

#### 5. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- 5.1 The evidence based technology report found limited evidence on the economic implications of hip resurfacing from two published articles and one HTA. Revision rates are important input factors in the prediction models, and no study estimated the revision rates using current data.



Although further study is necessary to include more current data, there is currently insufficient evidence to warrant a conclusion about the economic value of HR in a US setting.

## 6. 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.

- 6.1 Centers for Medicare and Medicaid Services (clarification at meeting) – does not have a national coverage decision. One local Wisconsin carrier covers HR as medically necessary in select patients requiring primary hip resurfacing due to the following conditions:
  - Non-inflammatory arthritis (degenerative joint disease) such as osteoarthritis, traumatic arthritis, avascular necrosis, or dysplasia / developmental dislocation of the hip.
  - Inflammatory arthritis, such as rheumatoid arthritis.
- 6.2 Guidelines – a search of the National Guideline Clearinghouse (NGC) returned zero potential guidelines on HR. No clinical guidelines related to HR procedures were found when the NGC database was searched.
  - Additional searching of the AAOS web site did not yield any guidelines specific to HR.
- 6.3 The following provides a summary of the National Institute for Health and Clinical Excellence (NICE) guidelines:
  - The NICE hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement.
    - Although there is sufficient short-term evidence to conclude that MOM hip resurfacing can be as effective as total hip replacement (THA) in patients less than 55 years, NICE acknowledges that there are no randomized controlled trials comparing MOM hip resurfacing arthroplasty with conventional THA. There are also no long-term (> 10 years) observational data on the outcomes associated with MOM HR devices.

## Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

## 7. Evidence availability and technology features

The committee concludes that the best available evidence on Hip Resurfacing has been collected and summarized.

- 7.1. Severe hip disease is a prevalent and burdensome disease. Current treatment using surgical total joint replacement (THA) is effective and well established in older patients (aged 60 to 80). However, for younger patients the risk of the artificial joint wearing out, and of its' durability for more active lifestyles has lead to need for alternative.
- 7.2. Hip resurfacing (HR) acts to preserve the bone and is thought to be more durable because the femoral head and neck are preserved, thus it may be an ideal "bridge" therapy to delay the need for later hip replacement. HR a more invasive and technically difficult surgery than THA (size and placement of cup; and soft tissue disruption).
- 7.3. In general, the committee noted that for a significant and invasive surgery, there is a paucity of high quality evidence (three RCTs are small and methodologically challenged and apply to non-FDA approved device) while remaining studies are mostly retrospective cohort studies.

Country wide data registries may provide the best information to date on critical issue of revision and complications. Committee agreed with evidence suggesting that more experienced surgeons have better outcomes and fewer complications, but that training for device implantation is not uniform or reviewed for quality.

- 7.4. The committee acknowledged that HR has had several iterations, being introduced and then discredited earlier, and now re-introduced with new materials and techniques, and that modern techniques were reviewed here, though lessons from earlier introduction may apply. The committee noted that even modern era HR has had dissemination issues: the Durom was recalled by the FDA due to mislabeling in 2007 and subsequently in 2008, the manufacturer, Zimmer, pulled the device due to surgeons not having adequate training for implantation (this is the device used in the RCTs).

## 8. Is it safe?

The committee concludes that the comprehensive evidence reviewed showed insufficient evidence to conclude that HR is safe: with five committee members voting unproven; three committee members voting equivalent; and two less safe. Key factors to the committee's conclusion included:

- 8.1. The committee agreed that the main safety question was whether HR provided lower morbidity, lower revision, or lower other complications. In general, evidence demonstrates a higher revision rate; and no difference in morbidity and complications.
- 8.2. The primary concern is the revision rates, but also identified femoral neck fracture (which leads to revisions) as another important complication.
- Femoral neck fractures: a primary theoretical advantage of HR is the durability and preservation of the hip bones, so the complication of a femoral neck fracture undermines this advantage and generally requires revision with THA. Femoral neck fracture rates ranged from .4 to 2.6% in short term and up to 5.4% in mid-term follow up. There may be an association with appropriate cup size and with smaller femoral component sizes (generally female) more prone to fracture.
  - Revision rates: overall evidence demonstrates higher revision rates in HR than THA; ranging from 0% to 7.8% in HR group and 0% to 4.3% in THA group. Rates in the Australian Joint Replacement Registry, with longest follow up (7 yr) and includes 125,004 THA and 10,263 HR, indicates that the cumulative revision rate for HR is 4.6% and THA is 3.4%. Analysis also revealed a significant difference in dysplasia patients' revision rates: 2% to 3% THA and 5% to 14% HR. Committee agreed that when needed, revision in THA patients is a more invasive and difficult surgery (with potential for more complications) than HR revision.
- 8.3. The committee acknowledged the concern regarding metal ions and agreed with the evidence report that more data and longer term information is needed. However, this issue is present with both THA and HR devices that are metal on metal.
- 8.4. The committee agreed that most perioperative adverse events stemmed from the technique of implantation itself, and reinforced the adequacy of training and experience.

## 9. Is it effective?

The majority of committee members conclude that the comprehensive evidence reviewed indicates that Hip Resurfacing is equivalent to THA.

- 9.1. The committee agreed that one key assumption is that patients cannot be active with THA; the other key assumption is that relatively younger patients may outlive a prosthesis and will have an easier second surgery (THA) if the first surgery is an HR.



- 9.2. The physical procedure does conserve bone; clinical expert experience indicates that a second THA surgery is much more complicated than a THA surgery after an HR.
- 9.3. Overall, there is agreement with the evidence report showing low level data of short to mid-term time frame that functional and pain outcomes are same and activity scores slightly higher for HR.
- 9.4. From evidence, data demonstrates two procedures are equivalent with tradeoffs in different benefits. Both surgeries appear equivalent at alleviating pain and improving function from severe hip disease.
- 9.5. HR is a more complicated surgery with higher (double) revision rates, but if successful, can provide a better opportunity for a second THA surgery and may provide slightly better activity level.
- 9.6. THA is surgically less complex with lower complication and revision rate, but second surgeries, if needed are more difficult and complicated and activity level may be more limited.
- 9.7. Committee members expressed concern that endorsement of HR may lead to encouragement of more surgery and in patients not previously being considered for surgery. Comparative trials and evidence are limited to patients that would otherwise be treated with THA.

#### **10. Evidence about the technology's special populations, patient characteristics and adjunct treatment**

- 10.1. The committee discussed selected population and patient characteristics of gender and component size, as well as dysplasia patients within the revision context.

#### **11. Is it cost-effective?**

The committee split on whether the evidence sufficiently addressed cost: with five members voting that costs are equivalent and five voting unproven (not sufficient data yet).

- 11.1. Committee acknowledged that the limited agency utilization experience to date indicated that HR and THA are equivalent in cost.
- 11.2. Committee agree with the evidence report that most cost studies utilized outdated revision rates (generally lower than showed for HR) and this significantly impacts cost analysis.

#### **Committee Decision**

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, agency and state utilization information. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee concluded that there is sufficient evidence to cover with conditions the use of Hip Resurfacing as an alternative to total hip arthroplasty. Primary considerations were that a majority of committee members concluded evidence demonstrated that HR is equivalent to THA in treating severe hip disease. With equivalence in efficacy at treating the condition demonstrated, this procedure is one where the trade-offs between THA and HR are between potentially better activity levels but higher risk of revision and complications, and these trade-offs should be discussed by patient and physician, within certain limits (the conditions imposed). Cost was not a significant factor.

Based on these findings for Hip Resurfacing, the committee voted 10 to 0 for coverage with conditions.



**Hip Resurfacing Coverage 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.

Hip Resurfacing Evidentiary Votes:

Is there sufficient evidence under some or all situations that Hip Resurfacing is:

	<b>Unproven (no)</b>	<b>Equivalent (yes)</b>	<b>Less (yes)</b>	<b>More (yes)</b>
<b>Effective</b>	3	7	0	0
<b>Safe</b>	5	3	2	0
<b>Cost-effective Overall</b>	5	5	0	0

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

<b>HTCC COMMITTEE COVERAGE DETERMINATION</b>			
	<b>Not covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
<b>Hip Resurfacing</b>	<b>0</b>	<b>0</b>	<b>10</b>

Outcome: The committee chair directed HTA staff to prepare a Findings and Decision document on Hip Resurfacing reflective of the majority vote for final approval at the next public meeting.

- Hip Resurfacing is a covered benefit with conditions. Total hip resurfacing arthroplasty as medically necessary as an alternative to total hip arthroplasty when all of the following conditions are met:
  1. Diagnosis of osteoarthritis or inflammatory arthritis;
  2. Individual has failed nonsurgical management and is a candidate for total hip arthroplasty; and
  3. The device is FDA approved

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## Health Technology Clinical Committee Findings and Coverage Decision

Topic: Electrical Neural Stimulation (ENS)

Meeting Date: October 30<sup>th</sup>, 2009

Final Adoption:

### Number and Coverage Topic

20091030A – Electrical Neural Stimulation

### HTCC Coverage Determination

Electrical Neural Stimulation is a **non-covered benefit**. This decision applies to use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g. in home use).

### HTCC Reimbursement Determination

#### ❖ Limitations of Coverage

- Not Applicable

#### ❖ Non-Covered Indicators

- The use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g., in home use).

#### ❖ Agency Contact Information

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

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## **Health Technology Background**

The Electrical Neural Stimulation (ENS) topic was selected and published in December 2008 to undergo an evidence review process. Pain is a very prevalent and burdensome condition. Back pain is the most commonly reported of all types with more than 25% of adults reporting low back pain in the prior 3 months, with pain most commonly reported among adults 45 years of age and over. Many treatments, increasing in number, are available to manage acute and chronic pain including physical therapies, medications, surgical intervention, neural blocks, psychotherapy, and complementary and alternative practices.

Pain is one of the most common causes of disability in the United States. Low back pain, headache, and joint pain, aching, or stiffness are among the most common complaints. Types of acute pain: procedural pain, pre-and postoperative pain, post-traumatic pain, dental procedures, and labor pain. Conditions that can lead to chronic pain: arthritis, low back pain, and other musculoskeletal problems. Transcutaneous electrical stimulation (TENS) is a commonly prescribed treatment. Estimates of use are limited, but there were 275,000 reported TENS prescriptions in 1991. Proponents estimate 50% - 80% of chronic pain patients and 6% - 44% of acute pain patients benefit from TENS. Although TENS has been widely adopted, it is unclear that benefit has been established for pain relief in high quality studies.

Treatment with TENS involves the transmission of electrical energy from an external stimulator to the peripheral nerve system via cutaneously placed conductive gel pads (electrodes). Usually have a single channel (with two electrodes) or dual channels (with four electrodes). Manner in which the current is delivered can vary in frequency, intensity, pulse width, electrode placement and duration.

In September 2009, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Electrical Neural Stimulation report is 102 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on October 30<sup>th</sup>, reviewed the report, including peer and public feedback, and heard agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.



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## Committee Findings

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

### **1. Evidence availability and technology features**

The committee concludes that the best available evidence on electrical neural stimulation has been collected and summarized.

- ENS devices use electrical stimulation of nerves via pads on the skin. However, ENS topics is made difficult to assess by the wide variance in different devices, differing placement locations, and delivering varying pulse, and frequency of stimulation, and duration at each treatment and over time. Cochrane reviews included different modalities in their reports which were grouped by different clinical indications.
- Electrical neural stimulation (ENS) is a commonly prescribed treatment that has been in use for over 30 years, is widely used and adopted despite unclear benefit.
- Evidence from eight Cochrane reports reviewing 86 randomized controlled trials and six additional randomized, controlled trials, provides a relatively large evidence base consisting of randomized trials, but the evidence is mostly insufficient, low quality data providing mixed results on a generally narrow outcome of short term pain relief.
- Given the variety of device types and conditions, the committee sought to focus discussion and consideration. The data from agencies on cost was associated with durable medical equipment purchase or rental of ENS devices and supplies, and CMS' policy was similar. Agency comments indicated that charges for use in facility are included in overall charges, not generally separable and managed through daily or unit caps the apply to broad group of services. The committee decided to limit deliberation and decision(s) to ENS prescribed for take home or outside clinic setting and excluded further consideration of ENS used as part of a clinician's in facility services (e.g. use in labor or use in physical therapy facility).

### **2. Is the technology safe?**

The committee concludes that the comprehensive evidence reviewed shows that the ENS technology is safe. Key factors to the committee's conclusion included:

- The committee agreed with the evidence report conclusions that indicated ENS is not associated with mortality.
- The evidence report concludes that most adverse effects were mild, most often associated with irritation at the electrode site or discomfort with the sensation of TENS current. No significant adverse outcomes identified, though studies may be underpowered for this event, the ENS devices are used to deliver small currents to the skin and no significant adverse complications would be expected.
- The devices have been in wide use for 30 years with no observed effects. A small issue for in home use and the possible unknown effect (long term) of over stimulation of nerve fibers was raised, but agreed unlikely.

### **3. Is the technology effective?**

The committee concludes that the comprehensive evidence reviewed shows that TENS is not more effective for treatment of acute or chronic pain. Note: consistent with overall decision, this conclusion applies to use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g. in home use).

- Overall, the committee agreed with the evidence based report that concluded, despite identification a over 80 randomized trials, the evidence is insufficient for evidence based conclusions about efficacy or effectiveness of ENS due to mostly low or very low quality studies (small numbers, lack of blinding, intermediate or insufficient outcomes, variable devices, indications and settings used, inadequate descriptions and controls, and measurements, conflicting results), though some indications and devices have somewhat higher quality evidence.
- The committee reviewed findings primarily for the chronic pain, low back, and knee osteoarthritis indications as these were noted as primary uses by agencies and/or had relatively higher levels of evidence (either quantity or design).
- No reliable information was available on important outcomes of reduction in analgesic medication, improvement in functional status, or quality of life.
- Pain – the primary outcome measured generally focused on short term outcomes with no evidence on long term use or outcomes although primary state costs and usage are for longer term. Low quality is insufficient to conclude whether ENS treatment provides or does not provide benefit. If any benefit demonstrated, evidence is limited by short term trial duration/follow up.
- While there was broad agreement on lack of evidence of benefit, the clinical issue of the value of a placebo effect for some patients who may then not need treatment with medication (generally opioids) where there are known risks and costs was discussed. There is no current evidence that ENS usage eliminates or reduces medication use, but this was not evaluated and clinical experience indicates it may effect decision making. A related factor discussed was that the issue was payment, not ability to access (many items such as specialized mattresses or pillows available to try but not insured benefit), and the in clinic treatment is not under consideration.
- The committee discussed the issue of comparators, ultimately deciding on treatment with ENS versus treatment without ENS.

#### **4. Is the technology cost-effective?**

The committee concludes that the comprehensive evidence review shows no published good quality evidence on ENS treatment.

- Committee noted that where efficacy and effectiveness are not established, cost effectiveness is premature. No quality studies have been produced, and the one included cost savings estimate is based on assumptions of decreased medication and physical therapy use, neither of which have been studied, reported on or demonstrated.
- Committee acknowledged the state agency costs of nearly \$3million over last four years, generally increasing and reaching nearly 1 million last year (900,000) in the durable medical equipment (DMS) costs.



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## 5. Medicare Decision and Expert Treatment Guidelines

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

- Centers for Medicare and Medicaid Services (2003) – CMS will cover the use of TENS for the relief of acute post-operative pain. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs. TENS devices, whether durable or disposable, may be used in furnishing this service. In cases where TENS is used for longer than 30 days, TENS may be covered as durable medical equipment (DME). PNT only covered if performed by a physician. No evidence cited for these decisions.
- Guidelines – a search of the National Guideline Clearinghouse (NGC) returned 8 potential guidelines on the use of TENS for pain management. Of those, 6 specifically described conditions for TENS use and provide specific recommendations. In general, very little information specific to the use of TENS with regard to chronic conditions like low back pain, rheumatoid arthritis, headache, and neuropathic pain were described. Two guidelines that described management of acute pain conditions, concluded that TENS therapy was generally not recommended. The following provides a summary of the guidelines that were most relevant:
  - (1) University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core – good evidence that TENS can be used as a non-pharmacological, physical method for the treatment of persistent pain in older adults; although, other therapies have been found to be useful, the evidence is still preliminary and inconclusive.
  - (2) American College of Occupational and Environmental Medicine (ACOEM) – the only recommendation was TENS therapy for low back pain; however, the evidence was described as limited and it was only recommended for select appropriate patients. All other ENS modalities were not recommended or described.
  - (3) Ottawa Panel evidence-based practice guidelines on electrotherapy for the management of rheumatoid arthritis – overall, only low frequency TENS applied to the hand and wrist showed a small clinical benefit.
  - (4) Institute for Clinical Systems Improvement (ICSI) – TENS units for migraine or muscle contraction headache have not been found to be more beneficial than placebo when evaluated in a controlled study.
  - (5) National Headache Foundation – Considering the inconvenience and the limited efficacy, this treatment was not recommended.
  - (6) European Federation of Neurological Societies (EFNS) – they concluded standard high-frequency TENS might be better than placebo.
  - (7) Stoke Rehabilitation Clinical Practice Guidelines – this guideline does not address the use of TENS for pain relief specifically, but describes TENS for decrease in spasticity, and increase in functional status (motor function, gait speed, passive shoulder range of motion, and sensation).
  - (8) American Pain Society – concluded there was insufficient evidence to accurately judge the efficacy of TENS versus other interventions for chronic low back pain or for acute low back pain. In a more recent guideline, TENS was not listed as an interventional therapy for patients with low back pain.

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**Committee Decision**

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, agency and state utilization information. The committee concluded that the current evidence on Electrical Neural Stimulation demonstrates that there is insufficient evidence to cover the use of Electrical Neural Stimulation. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee found that Electrical Neural Stimulation didn't have a mortality rate; morbidity from ENS was unusual and generally mild, most often associated with irritation at the electrode site or discomfort with the sensation of ENS current; and ENS showed insignificant data to conclude it was effective in reducing pain relief, satisfaction and Analgesic Consumption.

Based on these findings, the committee voted 8 to 2 to not cover Electrical Neural Stimulation for durable medical equipment usage (buying or renting the equipment for home use).

**Health Technology Clinical Committee Authority**

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