



**Health Technology Assessment  
Program Overview**

Josh Morse, Program Director  
Health Technology Assessment  
November 15, 2013



## Presentation Overview

**Today's Topics:**

- HTA Program Overview
- Hyaluronic Acid/ Viscosupplementation (Update)
- Hip Resurfacing (Update)





## HTA Background

- The Health Technology Assessment Program (HTA) is located within the Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
  - Safety
  - Efficacy/ Effectiveness
  - Cost-Effectiveness



## HTA Background

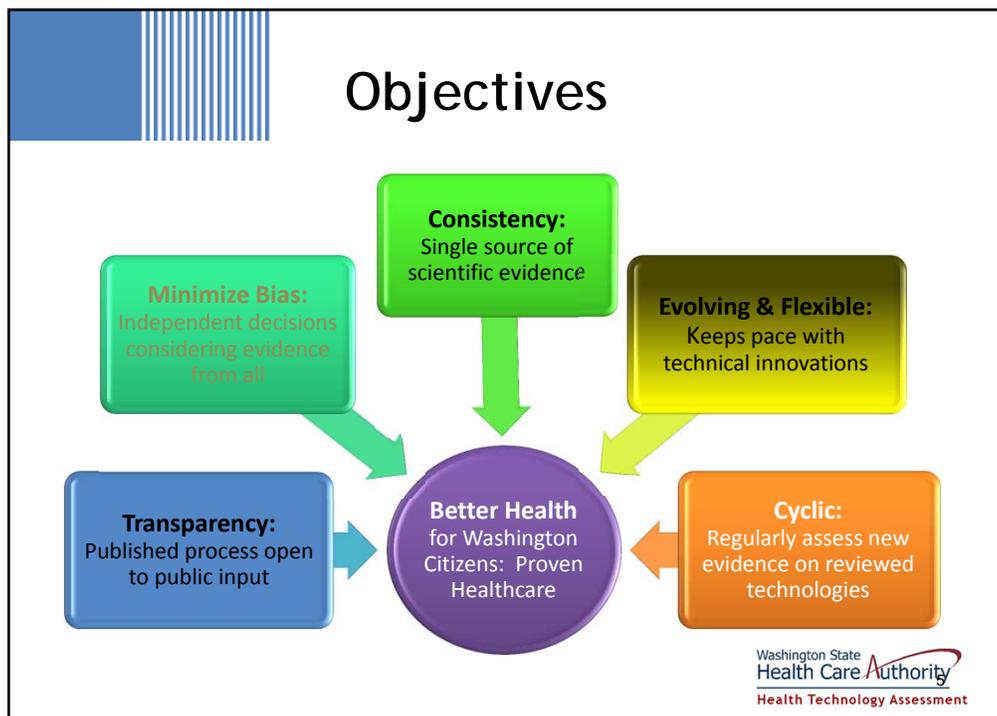
- Multiple state agency programs participate to identify topics and implement policy decisions:
  - Health Care Authority
    - Uniform Medical Plan
    - Medicaid
  - Labor and Industries
  - Corrections
- Implementation:
  - Agencies implement determinations of the HTA program within their existing statutory framework.

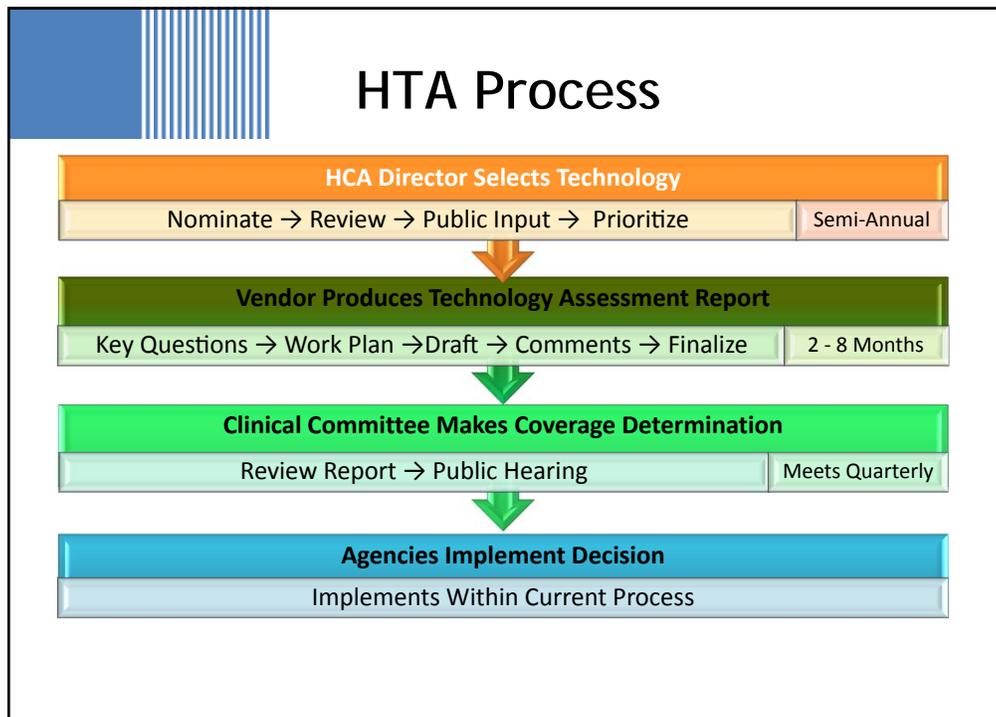


## Purpose: Pay for What Works

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners to determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.





## Principle Key Questions

- Is it safe?
- Is it effective?
- Does it provide value (i.e. improve health outcomes)?

Washington State  
Health Care Authority  
Health Technology Assessment



## HTA Values

**Transparency:** Publish topics, criteria, reports, conduct open meetings

**Best Evidence:** Formal, systematic process for review of selected health care technologies.

**Independent Decisions:** Committee of practicing clinicians make decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.



## HTCC Decision Basis

Clinical Committee decisions must give greatest weight to most valid and reliable evidence.

- Objective Factors for evidence consideration
  - Nature and source of evidence
  - Empirical characteristics of the studies or trials upon which evidence is based
  - Consistency of outcomes with comparable studies
- Additional evaluation factors
  - **Recency** (date of information)
  - **Relevance** (applicability of information to the key questions presented or participating agency programs and clients)
  - **Bias** (conflict of interest or political considerations)





## Topic Updates/Re-reviews

- Today's topics were previously reviewed by the HTA Program/Health Technology Clinical Committee
- HTA program law includes re-review of topics when new evidence could change a prior HTCC determination
- Hyaluronic Acid was identified for this update based on new evidence published in 2012
- Hip Resurfacing was identified for this update based on new evidence from large registries published since the original determination



## Technology Topics 2013-14

- ❖ Hyperbaric Oxygen (HBO2) Treatment
- ❖ Cervical Spinal Fusion for Degenerative Disc Disease
- ❖ Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation
- ❖ Cochlear Implants: Bi- versus Unilateral
- ❖ Cardiac Nuclear Imaging
- ❖ Carotid Artery Stenting
- Hyaluronic Acid/Viscosupplementation (Update)
- Hip Resurfacing (Update)
- ❖ Facet Neurotomy for Treatment of Facet Joint Pain
- ❖ Non-Pharmacological Treatments for Treatment-Resistant Depression
- ❖ Proton Beam Therapy





## How To Participate

- **Visit** the HTA Web site at our **NEW URL**: <http://www.hca.wa.gov/hta>
- **Join** the HTA stakeholder distribution list: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)  
Stakeholders notified of all program publications and meetings
- **Comment** on:
  - Proposed topics
  - Key questions
  - Draft & final reports
  - Draft decisions
- **Attend** HTCC public meetings  
All meeting materials posted on the web
- **Present** comments at Clinical Committee meetings
- **Nominate** health technologies for review



## HTA Contact Information

**NEW URL:** [hca.wa.gov/hta](http://hca.wa.gov/hta)

**Email:** [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

**Josh Morse**  
**Program Director**  
(360) 725-0839  
[Josh.Morse@hca.wa.gov](mailto:Josh.Morse@hca.wa.gov)





**Health Technology Clinical Committee**

**Date:** September 20, 2013

**Time:** 8:00 am – 5:00 pm

**Location:** SeaTac Airport Conference Center

**Adopted:**

Meeting materials and transcript are available on the HTA website at:  
[http://hta.hca.wa.gov/past\\_materials.html](http://hta.hca.wa.gov/past_materials.html)

**HTCC DRAFT MINUTES**

**Members Present:** C. Craig Blackmore, MD, MPH; Marie-Annette Brown, PhD, RN; Joann Elmore, MD MPH; David McCulloch, MD; Carson E. Odegard, DC, MPH; Richard C. Phillips, MD, MS, MPH; Seth Schwartz, MD, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh, MD

**HTCC FORMAL ACTION**

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. May 17, 2013, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

*Action:* Seven committee members approved the May 17, 2013 meeting minutes. Four members were absent.

- 3. Cochlear Implants: Bilateral versus Unilateral:** Chair referred members to the draft findings and decision and called for further discussion or objection. No comments were received on the draft Findings and Decision document.

Cochlear Implants: Bilateral versus Unilateral Draft Findings & Decision was approved and adopted by the committee.

*Action:* Seven committee members approved the Cochlear Implants: Bilateral versus Unilateral Draft Findings & Decision document. Two members abstained.

- 4. Catheter Ablation Procedures for Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. Thirteen comments were received on the draft decision. Committee discussed comments and determined to make no changes to the draft.

Catheter Ablation Procedures for Supraventricular Tachyarrhythmia Draft Findings & Decision was approved and adopted by the committee.

*Action:* Eight committee members approved the Cervical Spinal Fusion Findings & Decision document. One member abstained.

**Draft**

### 5. Cardiac Nuclear Imaging Scheduled and Open Public Comments:

The Chair called for public comments. Two individuals had scheduled time for public comments:

- James Caldwell, MD, Professor of Medicine & Radiology, University of Washington
- Neal Perlmutter, MD, American College of Cardiology

Presentation materials and conflict of interest forms are available with [September 20 meeting materials](#).

No open public comments were presented.

### Agency Utilization and Outcomes:

Kerilyn Nobuhara, MD, MHA, Senior Medical Consultant, Health Care Authority, presented the state agency utilization rates for Cardiac Nuclear Imaging to the committee. The full presentation is published with [September 20 meeting materials](#).

### Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Rita Redberg, MD, M.Sc., FACC, Professor of Clinical Medicine, UCSF Medical Center, San Francisco, CA

Daniel A. Ollendorf, MPH, of Institute for Clinical and Economic Review, presented the evidence review addressing Cochlear Implants. The full presentation is published with [September 20 meeting materials](#).

### Committee Discussion and Decision:

The HTCC reviewed and considered the Cardiac Nuclear Imaging technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. The evidence report focused on single photon emission computed tomography (SPECT) and positron emission tomography (PET). 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. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Cardiac Nuclear Imaging - SPECT	0	0	11
Cardiac Nuclear Imaging - PET	0	0	11

### Covered Conditions

- *Discussion:* The Chair called for discussion of conditions of coverage for Cardiac Nuclear Imaging following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

### Limitations of Coverage

Cardiac Nuclear Imaging is a **covered benefit with conditions including:**

#### SPECT

**Covered for patients with symptoms of myocardial ischemia (symptomatic) who are:**

- At high risk of coronary artery disease (CAD), or
- At low to intermediate risk of CAD, and
  - Have abnormal/indeterminate exercise treadmill test (ETT), or
  - Unable to perform ETT, or
  - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT.

**For patients with known CAD, monitoring:**

- Changes in symptoms

#### PET

**Covered** under the same conditions as SPECT when:

- SPECT is not technically feasible; or
- SPECT is inconclusive.

### Non-Covered Indicators

Cardiac Nuclear Imaging **is not a covered benefit** for:

- Asymptomatic patients\*
- Patients with known CAD and no changes in symptoms

\* Does not apply to pre-operative evaluation of patients undergoing high-risk non-cardiac surgery or patients who have undergone cardiac transplant.

The committee checked for availability of a Medicare decision. CMS has a national coverage determination (NCD) for SPECT that gives CMS regional contractors discretion with respect to clinical indications and limitations of coverage with one exception that SPECT may not follow an inconclusive PET scan for myocardial viability. For SPECT, the HTCC reviewed this NCD and the local decision. CMS has a NCD for PET Cardiac Nuclear Imaging. The committee's determination is in agreement with the NCD for SPECT and PET with regard to indications for testing. The committee did not address specific radiotracers for PET scanning.

Chair directed HTA staff to prepare a draft coverage determination document for the topic.

**6. Proton Beam Therapy Draft Key Questions:** Chair referred members to the draft key questions and called for further discussion. Committee reviewed the draft key questions and provided recommendations to Dan Ollendorf of ICER, the assigned review contractor.

**7. Carotid Artery Stenting:**

**Scheduled and Open Public Comments:** The Chair called for public comments. Three individuals scheduled time for public comments.

- Larry Dean, MD, Society for Cardiovascular Angiography and Interventions/ WA Chapter American College of Cardiology (Michael E. Ring, MD presented comments for Dr. Dean)
- Louis Kim, MD, American Association of Neurological Surgeons/ College of Neurological Surgeons/ WA State Association of Neurological Surgeons
- R. Torrance Andrews, MD, FSIR, Society of Interventional Radiology

Presentation materials and conflict of interest forms are available with [September 20 meeting materials](#).

**Agency Utilization and Outcomes:**

Gary Franklin, MD, MPH, Medical Director, Department of Labor and Industries, presented the state agency utilization rates for Carotid Artery Stenting to the committee. The full presentation is published with [September 20 meeting materials](#).

**Vendor Report and HTCC Q & A:**

The Chair introduced the clinical expert, Robert M. Bersin, MD, MPH, Medical Director, Structural Heart Services and Endovascular Services, Swedish Medical Center.

Andrea C. Skelly, PhD, MPH of Spectrum Research, Inc., presented the evidence review addressing Carotid Artery Stenting. The full presentation is published with [September 20 meeting materials](#).

**Committee Discussion and Decision**

The HTCC reviewed and considered the Carotid Artery Stenting technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, 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
Carotid Artery Stenting	0	0	11

### Covered Conditions

- *Discussion:* The Chair called for discussion of conditions of coverage for Carotid Artery Stenting following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

### Limitations of Coverage:

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

### Non-Covered Indicators

Carotid Artery Stenting of intracranial arteries is **not covered**.

### Definition of “high risk” includes:

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

**Definition of symptoms of carotid artery stenosis include:** carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient

monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale  $\geq 3$ ) shall be excluded from coverage.

The committee checked for availability of a Medicare coverage decision. There is a national coverage determination (NCD) for Carotid Artery Stenting (CAS). The committee reviewed the NCD and determined that based the availability of more recent study evidence to: cover extracranial CAS without a requirement of study participation for patient at high risk for CEA with stenosis of 50 to 70%; to cover without a requirement of study participation for asymptomatic patients at high risk of surgery for CEA with  $\geq 80\%$  stenosis. These criteria provide access to coverage similar to the NCD without study participation as a requirement.

The committee determined noncoverage for intracranial stents based on evidence indicating serious safety concerns, and recognizing that state agency programs may provide coverage in the context of appropriate clinical trials. The committee reviewed and considered available guidelines.

The Chair directed HTA staff to prepare a draft coverage determination document for the topic.

The Chair called for further comments. No further comments on review of Carotid Artery Stenting.

**8. Meeting adjourned.**

**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Cardiac Nuclear Imaging  
**Meeting Date:** September 20, 2013  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website at:  
[http://www.hta.hca.wa.gov/past\\_materials.html](http://www.hta.hca.wa.gov/past_materials.html)

**Number and Coverage Topic:**

20130920A – Cardiac Nuclear Imaging

**HTCC Coverage Determination:**

Cardiac Nuclear Imaging is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

**HTCC Reimbursement Determination:**

**Limitations of Coverage**

Cardiac Nuclear Imaging is a **covered benefit with conditions including:**

**SPECT** (Single Photon Emission Computed Tomography)

**Covered for patients with symptoms of myocardial ischemia (symptomatic) who are:**

- At high risk of coronary artery disease (CAD), or
- At low to intermediate risk of CAD, and
  - Have abnormal/indeterminate exercise treadmill test (ETT), or
  - Unable to perform ETT, or
  - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT.

**For patients with known CAD, monitoring:**

- Changes in symptoms

**PET** (Positron Emission Tomography)

**Covered** under the same conditions as SPECT when:

- SPECT is not technically feasible; or
- SPECT is inconclusive.

**Draft**

**Non-Covered Indicators**

Cardiac Nuclear Imaging **is not a covered benefit** for:

- Asymptomatic patients\*
- Patients with known CAD and no changes in symptoms

\* Does not apply to pre-operative evaluation of patients undergoing high-risk non-cardiac surgery or patients who have undergone cardiac transplant.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

---

Draft

**HTCC Coverage Vote and Formal Action**

**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, and agency and state utilization information. The committee concluded that the current evidence on Cardiac Nuclear Imaging demonstrates that there is sufficient evidence to cover with conditions. 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. Based on these findings, the committee voted to cover with conditions Cardiac Nuclear Imaging.

<b>HTCC Committee Coverage Determination Vote</b>			
	<b>Not Covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
Cardiac Nuclear Imaging - SPECT	0	0	<b>11</b>
Cardiac Nuclear Imaging - PET	0	0	<b>11</b>

**Discussion**

The Chair called for discussion of conditions of coverage for Cardiac Nuclear Imaging following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

**Limitations of Coverage**

Cardiac Nuclear Imaging is a **covered benefit with conditions including:**

**SPECT** (Single Photon Emission Computed Tomography)

**Covered for patients with symptoms of myocardial ischemia (symptomatic) who are:**

- At high risk of coronary artery disease (CAD), or
- At low to intermediate risk of CAD, and
  - Have abnormal/indeterminate exercise treadmill test (ETT), or
  - Unable to perform ETT, or
  - Electrocardiogram (ECG) abnormality that prevents accurate interpretation of ETT.

**For patients with known CAD, monitoring:**

- Changes in symptoms

**PET** (Positron Emission Tomography)

**Covered** under the same conditions as SPECT when:

- SPECT is not technically feasible; or
- SPECT is inconclusive.

**Draft**

**Non-Covered Indicators**

Cardiac Nuclear Imaging **is not a covered benefit** for:

- Asymptomatic patients\*
- Patients with known CAD and no changes in symptoms

\* Does not apply to pre-operative evaluation of patients undergoing high-risk non-cardiac surgery or patients who have undergone cardiac transplant.

**Action**

The committee Chair directed HTA staff to prepare a Findings and Decision document on Cardiac Nuclear Imaging reflective of the majority vote for final approval at the next public meeting.

The committee checked for availability of a Medicare decision. CMS has a national coverage determination (NCD) for SPECT that gives CMS regional contractors discretion with respect to clinical indications and limitations of coverage with one exception that SPECT may not follow an inconclusive PET scan for myocardial viability. For SPECT, the HTCC reviewed this NCD and the local decision. CMS has a NCD for PET Cardiac Nuclear Imaging. The committee's determination is in agreement with the NCD for SPECT and PET with regard to indications for testing. The committee did not address specific radiotracers for PET scanning.

**Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-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 (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that 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 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 its 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.

**Draft**

**Cardiac Nuclear Imaging**  
*Draft Findings & Decision*  
*Timeline and Overview of Comments*

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Cardiac Nuclear Imaging

<b>Category</b>	<b>Comment Period</b> <i>October 8 - 22, 2013</i>	<b>Cited Evidence</b>
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
<b>Total</b>	<b>0</b>	<b>0</b>

No comments were submitted.

<b>Technology Assessment Timeline</b>		
<b>Study Stage</b>	<b>Date</b>	<b>Public Comment Days</b>
Technology recommendations published	November 1, 2011	
<b>Public comments due</b>	<b>November 15, 2011</b>	<b>16</b>
Selected technologies published	November 29, 2011	
<b>Public comments due</b>	<b>December 29, 2011</b>	<b>31</b>
Draft Key Questions published	March 21, 2013	
<b>Public comments due</b>	<b>April 8, 2013</b>	<b>19</b>
Final Key Questions published	April 29, 2013	
Draft report published	June 26, 2013	
<b>Public comments due</b>	<b>July 22, 2013</b>	<b>32</b>
Final report published	August 19, 2013	
Public meeting date	September 20, 2013	
Findings & decision published	October 8, 2013	
<b>Public comments due</b>	<b>October 22, 2013</b>	<b>15</b>



**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Carotid Artery Stenting  
**Meeting Date:** September 20, 2013  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website at:  
[http://www.hta.hca.wa.gov/past\\_materials.html](http://www.hta.hca.wa.gov/past_materials.html)

**Number and Coverage Topic:**

20130920B – Carotid Artery Stenting

**HTCC Coverage Determination:**

Carotid Artery Stenting is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

**HTCC Reimbursement Determination:**

**Limitations of Coverage:**

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

**Non-Covered Indicators**

Carotid Artery Stenting of intracranial arteries is **not covered**.

**Definition of high risk includes:**

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;
- Contralateral carotid occlusion;
- Recent myocardial infarction (MI);

**Draft**

- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

**Definition of symptoms of carotid artery stenosis include:** carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale  $\geq$  3) shall be excluded from coverage.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

## HTCC Coverage Vote and Formal Action

### *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, and agency and state utilization information. The committee concluded that the current evidence on Carotid Artery Stenting demonstrates that there is sufficient evidence to cover with conditions. 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. Based on these findings, the committee voted to cover with conditions Carotid Artery Stenting.

### Carotid Artery Stenting

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Carotid Artery Stenting	0	0	11

### *Discussion*

The Chair called for discussion of conditions of coverage for Carotid Artery Stenting following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

#### **Limitations of Coverage:**

Concurrent with the placement of a Food and Drug Administration (FDA) -approved carotid stent and an FDA-approved or -cleared embolic protection device; and in accredited facilities as determined by the state agencies, the following additional criteria apply:

- For patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis >50%.
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis ≥80%.

#### **Non-Covered Indicators**

Carotid Artery Stenting of intracranial arteries is **not covered**.

#### **Definition of high risk includes:**

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA. Significant comorbid conditions include, but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 %;
- Unstable angina;
- Contralateral carotid occlusion;

**Draft**

- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

**Definition of symptoms of carotid artery stenosis include:** carotid transient ischemic attack (distinct focal neurological dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale  $\geq$  3) shall be excluded from coverage.

### **Action**

The committee checked for availability of a Medicare coverage decision. There is a national coverage determination (NCD) for Carotid Artery Stenting (CAS). The committee reviewed the NCD and determined that based the availability of more recent study evidence to: cover extracranial CAS without a requirement of study participation for patient at high risk for CEA with stenosis of 50 to 70%; to cover without a requirement of study participation for asymptomatic patients at high risk of surgery for CEA with  $\geq$ 80% stenosis. These criteria provide access to coverage similar to the NCD without study participation as a requirement.

The committee determined noncoverage for intracranial stents based on evidence indicating serious safety concerns, and recognizing that state agency programs may provide coverage in the context The committee Chair directed HTA staff to prepare a Findings and Decision document on Carotid Artery Stenting reflective of the majority vote for final approval at the next public meeting.

### **Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-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 (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that 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 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 its 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.

**Draft**

**Carotid Artery Stenting**  
*Draft Findings & Decision*  
*Timeline and Overview of Comments*

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Carotid Artery Stenting.

<b>Category</b>	<b>Comment Period</b> <i>October 8 - 22, 2013</i>	<b>Cited Evidence</b>
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	1
<b>Total</b>	0	1

<b>Technology Assessment Timeline</b>		
<b>Study Stage</b>	<b>Date</b>	<b>Public Comment Days</b>
Technology recommendations published	November 1, 2011	
<b>Public comments due</b>	<b>November 15, 2011</b>	<b>16</b>
Selected technologies published	November 29, 2011	
<b>Public comments due</b>	<b>December 29, 2011</b>	<b>31</b>
Draft Key Questions published	November 26, 2012	
<b>Public comments due</b>	<b>December 11, 2012</b>	<b>16</b>
Final Key Questions published	January 17, 2013	
Draft report published	June 28, 2013	
<b>Public comments due</b>	<b>July 30, 2013</b>	<b>33</b>
Final report published	August 15, 2013	
Public meeting date	September 20, 2013	
Findings & decision published	October 8, 2013	
<b>Public comments due</b>	<b>October 22, 2013</b>	<b>15</b>





The Society for Cardiovascular  
Angiography and Interventions



Washington  
CHAPTER

October 23, 2013

Josh Morse, MPH, Program Director  
Washington State Health Care Authority  
Health Technology Assessment Program  
PO Box 42712  
Olympia, WA 98504-2712

**\*\*\*Submitted electronically via email [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)\*\*\***

RE: Health Technology Clinical Committee Draft Findings and Decision - 20130920B - Carotid Artery Stenting

Dear Mr. Morse:

The Society for Cardiovascular Angiography and Interventions and the Washington Chapter of the American College of Cardiology would like to congratulate the Washington State HTA on the careful consideration of the data on Carotid Stenting as well as the provision for limiting coverage to certified carotid stenting facilities. We would like to suggest that the Washington State HTA consider that either the Intersocietal Accreditation Commission (IAC) or the Accreditation for Cardiovascular Excellence (ACE) or similar certifying bodies to more thoroughly vet those centers that desire to participate in providing carotid stenting to their patients. Mandatory data collection on outcomes could be done at these centers either via existing the Washington State Clinical Outcomes Assessment Program (COAP) or other existing carotid data collection mechanisms (Society of Vascular Surgery or ACC-National Cardiovascular Data registries).

We applaud the extension of coverage to asymptomatic patients with an 80% or greater stenosis especially given that many, if not all manufacturers' carotid stenting registries, either are closed or likely will close soon which would significantly adversely impact asymptomatic patients' access to FDA approved therapies and which impacts their choice of an important alternative to surgery given current CMS coverage restrictions.

We strongly urge, however, that the Washington State HTA consider extending coverage to non-high risk patients with significant carotid artery stenosis in line with the current FDA approval for the procedure. We feel that the excellent outcomes in the CREST study should be considered separately from the previous European carotid stenting studies which were performed in a much less rigorous fashion with operators who were not rigorously trained in carotid stenting nor

Josh Morse, MPH, Program Director

October 23, 2013

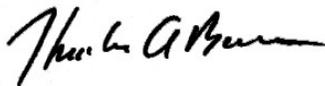
Page 2 of 2

routinely used embolic protection devices. Additionally, the recent excellent outcomes that were reported in the CHOICE registry (VIVA 2013: Vascular Interventional Advances conference, presentation October 2013) of high risk patients compared favorably with the outcomes in standard risk patients from CREST. This suggests that, with modern 2nd generation carotid stenting devices, the outcomes in standard risk patients would be even better than those previously reported in CREST.

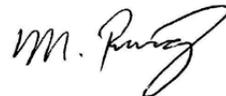
It would appear, therefore, that the totality of evidence in careful analyses of carotid stenting performed by well-trained operators in high quality centers would support the current FDA approval of the devices which in turn should allow treatment of standard risk patients in addition to high risk patients with significant carotid artery disease.

Thank you for allowing SCAI and the members of the Carotid Stenting Committee of SCAI to weigh in on this very important matter. Once again, we salute your efforts in the thorough evaluation of the carotid stenting data and urge you to give strong consideration to our additional suggestions for action.

Sincerely,



Theodore A. Bass, MD, FSCAI  
FSCAI  
SCAI President, 2012-2013



Michael E. Ring, MD, FACC,  
Governor, WA Chapter, ACC

cc: Margaret Dennis, Program Manager, HTAP  
Christine Masters, Program Specialist, HTAP  
Richard Smalling, MD, PhD, FSCAI, Chairman, SCAI Carotid Stenting Committee  
William Gray, MD, SCAI, Co-Chairman, SCAI Carotid Stenting Committee  
Peter Duffy, MD, FSCAI, Chairman, SCAI Advocacy Committee  
Steve Gigliotti, MD, FSCAI, Co-Chairman, SCAI Advocacy Committee  
Tony Farah, MD, FSCAI, Co-Chairman, SCAI Advocacy Committee  
Norm Linsky, SCAI, Executive Director  
Wayne Powell, SCAI, Sr. Sr. Director, Advocacy and Government Relations  
Dawn R. Hopkins, SCAI, Director, Reimbursement and Regulatory Affairs