Washington State Health Care Authority
Health Technology Assessment

Health Technology Clinical Committee
Date: September 20, 2013
Time: 8:00 am – 5:00 pm
Location: SeaTac Airport Conference Center
Adopted: November 15, 2013

Meeting materials and transcript are available on the HTA website at:
http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

HTCC 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.

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 ≥ 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 >=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.