

Health Technology Clinical Committee

Date: March 22, 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

HTCC MINUTES

<u>Members Present:</u> C. Craig Blackmore MD, MPH; Marie-Annette Brown PhD, RN; Joann Elmore, MD MPH; 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

Members Absent: David McCulloch, 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. November 16, 2012, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

<u>Action:</u> Eight committee members approved the November 16, 2012 meeting minutes. Three members were absent.

3. Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Draft Findings & Decision: Chair referred members to the draft findings and decision and called for further discussion or objection.

Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Draft Findings & Decision was approved and adopted by the committee.

<u>Action:</u> Nine committee members approved the Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Findings & Decision document. Two members were absent.

4. Vitamin D Screening and Testing Draft Findings & Decision: Chair referred members to the draft findings and decision and called for further discussion or objection.

Vitamin D Screening and Testing Draft Findings & Decision was approved and adopted by the committee.

<u>Action:</u> Nine committee members approved the Vitamin D Screening and Testing Findings & Decision document. Two members were absent.

5. Hyperbaric Oxygen Therapy (HBOT) for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions.

Scheduled and Open Public Comments:

The Chair called for public comments. One individual scheduled time for public comments:

• Karen Stanek, MD, Northwest Medical Rehabilitation

Presentation materials and conflict of interest form are available with March 22 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 Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions to the committee. The full presentation is published with March 22 meeting materials.

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Neil Hampson, MD, Past-President, Undersea and Hyperbaric Medical Society, Physician Emeritus, Virginia Mason Medical Center, Seattle, WA.

Karen Crotty, PhD, MPH of Hayes, Inc, presented the evidence review addressing Hyperbaric Oxygen Therapy. The full presentation is published with <u>March 22 meeting materials</u>.

Committee Discussion and Decision:

The HTCC reviewed and considered the Hyperbaric Oxygen Therapy 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.

- <u>Discussion</u>: The Chair called for discussion of conditions of coverage for Hyperbaric Oxygen Therapy 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:

Hyperbaric Oxygen Therapy is a covered benefit for:

- Crush injuries and suturing of severed limbs. HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened;
- Compromised skin grafts and flaps (not for primary management of wounds);
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management;
- Osteoradionecrosis as an adjunct to conventional treatment;

- For prevention of osteoradionecrosis associated with tooth extraction in a radiated field;
- Soft tissue radionecrosis as an adjunct to conventional treatment;
- o Diabetic wounds in patients who meet the following three criteria:
 - Patient has type I or type II diabetes and has a wound that is due to diabetes;
 - Patient has a wound classified as Wagner grade III or higher; and
 - Patient has failed an adequate course of standard wound therapy.

Non-covered Indications :

- Brain injury including traumatic (TBI) and brain injury chronic (excluding stroke)
- Cerebral Palsy
- Multiple Sclerosis
- Headache/migraine
- Sensorineural hearing loss
- Thermal burns
- Other non-healing wounds

The committee checked for availability of a Medicare decision. The Centers for Medicare & Medicaid Services (CMS) cover Hyperbaric Oxygen Therapy in either a mono-place or multi-chamber for a number of indications. For conditions addressed by the CMS National Coverage Determination and the HTA review, the HTCC findings agree with the CMS policy.

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

6. Spinal Cervical Fusion for Degenerative Disc Disease:

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

- Joseph Cheng, MD, American Association of Neurological Surgeons/ Congress of Neurological Surgeons
- Jason Lerner, Director Marketing Access, De Puys Synthes
- David Flum, MD, Spine Surgical Care and Outcomes Assessment Program (Spine SCOAP)

One organization submitted a letter in lieu of a scheduled presentation:

• Deana SCearce, JD, Director, State Government Affairs, Medtronic, Inc.

Presentation materials and conflict of interest forms are available with March 22 meeting materials...

No open public comments were presented.

Agency Utilization and Outcomes:

Gary Franklin, MD, MPH, Medical Director, Department of Labor and Industries, presented the state agency utilization rates for Cervical Spinal Fusion to the committee. The full presentation is published with March 22 meeting materials.

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Trent Tredway, MD, Director, Minimally Invasive Spine Surgery, Department of Neurological Surgery, and Associate Professor University of Washington School of Medicine.

Daniel A. Ollendorf, MPH, ARM, of the Institute for Clinical and Economic Review, presented the evidence review addressing Cervical Spinal Fusion. The full presentation is published with <u>March 22 meeting materials</u>.

Committee Discussion and Decision

The HTCC reviewed and considered the Cervical Spinal Fusion 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 | |
| Cervical Spinal Fusion | 0 | 0 | 10 | |

• <u>Discussion</u>: The Chair called for discussion of conditions of coverage for Cervical Spinal Fusion 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:

Cervical Spinal Fusion is a covered benefit for patients with signs and symptoms of radiculopathy and advanced imaging evidence of corresponding nerve root compression and failure of conservative (non-operative) care.

Cervical Spinal Fusion is not a covered benefit for neck pain without evidence of radiculopathy or myelopathy.

The committee checked for availability of a Medicare coverage decision. There is no national coverage determination (NCD) for any form of fusion surgery. Local coverage decisions (LCDs) are limited to spinal fusion for *lumbar* degenerative disc disease.

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 Cervical Spinal Fusion.

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| 7. | The Chair called for committee review of draft key questions open for public comment: Cardiac Nuclear Imaging; and Hyaluronic Acid / Viscosupplementation (re-review). HTA staff reminded committee members of the open comment period for key questions; committee reviewed draft key questions. |
| | Meeting adjourned. |
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