Washington State Health Care Authority Health Technology Assessment

Health Technology Clinical Committee

Date:November 20, 2015Time:8:00 am - 5:00 pmLocation:SeaTac Conference Center, SeaTac, WAAdopted:January 15, 2016

Meeting materials and transcript are available on the HTA website at:

www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx

HTCC MINUTES

<u>Members Present:</u> C. Craig Blackmore, MD, MPH; Gregory Brown, MD, PhD; Joann Elmore, MD MPH; Louise Kaplan, PhD, ARNP; David K. McCulloch, MD, FRCP; Carson Odegard DC, 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.** July 10, 2015 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 July 10, 2015 meeting minutes. Three members abstained.

3. Lumbar Fusion for Patients with Degenerative Disc Disease:

Agency Utilization and Outcomes:

Gary Franklin, Medical Director, Washington Department of Labor and Industries presented the state agency utilization rates for Lumbar Fusion to the committee. The full presentation is published with <u>November 20, meeting materials</u>.

Scheduled and Open Public Comments:

The Chair called for public comments. Comments were provided by:

- Jens R. Chapman, MD, Swedish Neuroscience Institute; Rod J. Oskouian, MD; Charles Nussbaum, MD, Virginia Mason; Marjorie Wong, MD; Matthew Fewel, MD (not present), representing WA State Association of Neurological Surgeons, American Association of Neurological Surgeons, Seattle Science Foundation, Congress of Neurological Surgeons.
- Trent Tredway, MD
- David Yam, MD

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Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert for Lumbar Fusion, Neal Shonnard, MD, Rainier Orthopedic Institute, Associate Director, The Spine SCOAP Registry.

Dan A. Ollendorf, PhD, presented the evidence review of **Lumbar Fusion for Patients with Degenerative Disc Disease Uncomplicated by Comorbid Spinal Conditions**. The full presentation is published with <u>November 20, meeting materials</u>.

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 state agency utilization information. The committee concluded that the current evidence regarding Lumbar Fusion for Degenerative Disc Disease is less safe than alternative treatments though it may be more effective than usual care, but is equivalent in efficacy when compared to more intensive physical modalities.

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 not cover **Lumbar Fusion for Degenerative Disc Disease Uncomplicated by Comorbid Conditions**. [See transcript for full committee deliberations.]

HTCC Committee Coverage Determination Vote:

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Lumbar Fusion for Patients with Degenerative Disc Disease	10	1	0
Degenerative Disc Disease	10	1	0

Discussion

The committee discussed the meaning of "uncomplicated degenerative disc disease" for this review and noted for the record that the population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

Action

The committee checked for availability of Medicare national coverage decisions (NCDs). There are no national or local coverage determinations for lumbar fusion that pertain to Washington State.

The committee discussed clinical guidelines identified for Lumbar Fusion including guidelines from the following organizations:

American Association of Neurological Surgeons (AANS) (2014) American Pain Society (APS) (2009)

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> Dr. Robert Bree Collaborative (2014) International Society for the Advancement of Spine Surgery (ISASS) (2015) National Institute for Health Care and Excellence (NICE) (2009) North American Spine Society (2014) Washington State Department of Labor and Industries (2009)

The Chair noted differences between the committee determination and some of the guidelines. The following reasons for the differences were cited by the committee: availability of information not considered in some guidelines, committee consideration of the long-term follow-up data in studies, concerns with potential adverse effects from surgery, concerns about cost-effectiveness of surgery versus non-invasive alternatives. The committee determination agreed with some of the guidelines.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Lumbar Fusion for degenerative disc disease reflective of the majority vote for final approval at the next public meeting.

6. Robert Mootz, DC, Associate Medical Director, WA Department of Labor and Industries presented the state agency utilization rates for Tympanostomy Tubes in Children to the committee. The full presentation is published with <u>November 20</u>, meeting materials.

Scheduled and Open Public Comments:

The Chair called for public comments. No comments were presented.

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert for Tympanostomy Tubes, Carol J. MacArthur, MD, Professor, Otolaryngology, Head and Neck Surgery, Oregon Health and Science University.

Daniel Ollendorf, PhD, ICER, Inc. presented the evidence review addressing Tympanostomy Tubes in Children. The full presentation is published with <u>November 20, meeting materials</u>.

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 state agency utilization information. The committee concluded that the current evidence regarding 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 Tympanostomy Tubes. [See transcript for full committee deliberations.]

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HTCC Committee Coverage Determination Vote:

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Tympanostomy Tubes for AOM	0	11	0
Tympanostomy Tubes for OME	0	11	0

Discussion

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

Limitations

Patients aged 16 years and younger

For AOM – Acute Otitis Media:

- 1. Cover if AOM with complications or individuals immunocompromised or otherwise at-risk for complications of infection, OR
- 2. With 3 episodes of AOM in the last 6 months or 4 episodes in last 12 months with one occurring in the last 6 months and presence of effusion at the time of assessment for surgical candidacy.

OME – Otitis Media with Effusion

- 1. Cover if the duration of effusion is 3 months or greater, AND there is documented hearing loss, OR
- 2. At-risk children:
 - a. Children at risk for persistent effusion based on anatomic abnormalities, OR
 - b. Children at disproportionate risk of hearing loss, such as speech delay, underlying sensory-neuro hearing loss, or cognitive disorders.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). There is no NCD for tympanostomy tubes.

The committee discussed clinical guidelines identified for tympanostomy tubes including guidelines from the following organizations:

The American Academy of Otolaryngology - Head and Neck Surgery Foundation (2013)

American Academy of Pediatrics (2013)

British Columbia Medical Association, British Columbia Ministry of Health Services, Guidelines and Protocols Advisory Committee

National Institute for Health and Care Excellence (NICE)

The Chair noted lack of concordance among some of the guidelines. The committee determination agreed with some of the guidelines; differences were cited as due to interpretation of the evidence.

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The committee Chair directed HTA staff to prepare a findings and decision document on tympanostomy tubes reflective of the majority vote for final approval at the next public meeting.

- 7. Josh Morse, HTA Program Director presented a status update on HTA technology assessments now in process and those scheduled for 2016.
- 8. The chair presented closing comments on the occasion of his departure from HTCC membership.
- 9. Meeting adjourned.