Washington State Health Care Authority

Health Technology Clinical Committee

Date: January 20, 2017
Time: 8:00 am – 5:00 pm
Location: SeaTac Conference Center, SeaTac, WA
Adopted: March 17, 2017

Meeting materials and transcript are available on the HTA website at:
www.hca.wa.gov/about-hca/health-technology-assessment/meetings-and-materials

Final HTCC Minutes

Members present: John Bramhall, MD, PhD; Gregory Brown, MD, PhD; Joann Elmore, MD, MPH; Chris Hearne, RN, DNP, MPH; Laurie Mischley, ND, PhD, MPH; Carson Odegard, DC, MPH; Seth Schwartz, MD, MPH; Christopher Standaert, MD; Kevin Walsh, MD; Tony Yen, MD
Clinical experts: Jon Montgomery McClellan, MD; Rod J. Oskouian, Jr., MD.

HTCC Formal Action

1. **Call to order:** Dr. Standaert, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented upcoming topics for committee meetings.
3. **November 18, 2016 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve November 18, 2016 minutes as written, seconded. Committee voted to accept the minutes.

   Action: Nine committee members approved the November 18, 2016 meeting minutes.
4. **Negative pressure wound therapy for home use – Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. One comment was received on the draft decision. The committee reviewed and discussed the comment which included recommended changes to clarify the intent of the determination. The committee modified the draft. Staff was directed to change the final determination per the approved comments.

   Action: Ten committee members voted to approve the negative pressure wound therapy findings and decision as amended.
5. **Fecal microbiota transplantation draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision.

   Action: Ten committee members voted to approve the fecal microbiota therapy findings and decision.

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6. Pharmacogenomic testing for selected conditions:

The chair introduced Jon (Jack) McClellan, MD, Professor, Department of Psychiatry and Behavioral Sciences, University of Washington, Seattle.

Agency utilization and outcomes: Charissa Fotinos, MD, MSc, Deputy Chief Medical Officer, Health Care Authority, presented the state agency perspective for Pharmacogenomics Testing for Selected Conditions. The full presentation is published with the January 20, meeting materials.

Scheduled and open public comments: The chair called for public comments. Comments provided by:

- Nathan Roe, PhD, Medical Science Liaison, Assurex Health
- Jim Pollard, National Account Manager, Government Accounts, Assurex Health

Public presentations are published with the January 20, meeting materials.

Vendor report / HTCC question and answer:

Margaret A. Piper, PhD, MPH, Hayes, Inc. presented the evidence review of *Pharmacogenomic testing for selected conditions*. The full presentation is published with the January 20, meeting materials.

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 evaluated the available evidence. The committee discussed and voted on the evidence for use of pharmacogenomic testing compared to current alternative strategies. A majority of committee members found the technology unproven for safety, efficacy and cost-effectiveness based on the quality of available evidence. The committee considered 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 pharmacogenomic testing for selected conditions.

	Not covered	Covered under certain conditions	Covered unconditionally
Pharmacogenomic testing for selected conditions	7	3	0

Discussion

The committee reviewed and discussed the available studies of pharmacogenomics. Details of study design, inclusion criteria and other factors affecting or potentially affecting study quality were discussed.

Limitations

Not applicable.

Action

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

The committee discussed clinical guidelines identified for pharmacogenomic testing for select conditions from the following organizations:

- Clinical practice guidelines: Depression in adolescents and young adults (2010)
- Position Statement : The value of antidepressants in the treatment of unipolar depression (2011) European Psychiatric Association
- Adult Depression in Primary Care (2016) ICIS
- Clinical Practice Guidelines for the Management of Major Depressive Disorders (2016) VA/DoD
- World Federation of Societies for Biological Treatment of Unipolar Depressive Disorders (2013)
- Practice Guidelines for the treatment of Patients with Panic Disorders (2009) American Psychiatric Association (APA)
- Practice Guidelines for the Treatment of Patients with Substance Use Disorders (2006) APA
- Guidelines: Pharmacological management of substance abuse, harmful use, addiction and comorbidity (2005) BAP
- Expert Group Consensus Guidelines: Focus on the therapeutic monitoring of antidepressants (2005) AGNP

The committee chair directed HTA staff to prepare a findings and decision document for pharmacogenomic testing for selected conditions reflective of the majority vote for public comment, followed by consideration for final approval at the next public meeting.

7. **Updates:** HTA reviews in progress- Josh Morse, HTA program director.

8. **Artificial disc replacement – Re-review**

The chair introduced Rod J. Oskouian Jr, MD, Chief of Spine and Co-Director, Complex and Minimally Invasive Spine Fellowship Program at the Swedish Neuroscience Institute.

Agency utilization and outcomes: Gary Franklin, MD, MPH, Medical Director for the Washington State Department of Labor and Industries, presented the state agency perspective and utilization and cost data to the committee. The presentation is published with the January 20, meeting materials.

Scheduled and open public comments: The chair called for public comments. Comments provided by:

- Jens Chapman, MD, Washington State Association of Neurological Surgeons, American Association of Neurological Surgeons, North American Spine Society, Congress of Neurological Surgeons
- Daniel Elskens, MD, Washington State Association of Neurological Surgeons, American Association of Neurological Surgeons, North American Spine Society, Congress of Neurological Surgeons

Public presentations are published with the January 20, meeting materials.

Vendor report and HTCC Q & A:

Andrea C. Skelly, PhD, MPH, Spectrum Research, Inc. presented the evidence review addressing artificial disc replacement. Find the full presentation published with the January 20, meeting materials.

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 on lumbar and cervical artificial disc replacement should be considered and voted on separately. The committee also determined that current evidence is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of artificial disc for these conditions compared to current alternative strategies. The committee considered 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 artificial disc replacement and separately voted to cover with conditions cervical artificial disc replacement.

	Not covered	Covered under certain conditions	Covered unconditionally
Lumbar artificial disc replacement	10	0	0
Cervical artificial disc replacement	0	10	0

Discussion

The committee reviewed and discussed the available studies of lumbar artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that lumbar artificial discs replacements were unproven for safety and unproven for

effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to not cover lumbar artificial disc replacement.

The committee reviewed and discussed the available studies of cervical artificial disc replacement. Details of study design, inclusion criteria and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that cervical artificial discs replacements were at least equivalent for safety and effectiveness compared to alternatives for some conditions, and unproven for cost-effectiveness. A majority of the committee voted to cover with conditions, cervical artificial disc replacement

Limitations

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletal mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patient must have advanced imaging or clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For two-level procedures, objective evidence of radiculopathy, myelopathy, or spinal cord compression at two consecutive levels is required.

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does have a NCD for lumbar artificial disc replacement.

The committee discussed clinical guidelines identified for cervical artificial disc replacement from the following organizations:

- Diagnosis and treatment of Cervical Radiculopathy from Degenerative Disorders (2010) North American Spine Society
- Cervical spine injury medical treatment guidelines (2014) State of Colorado Department of Labor and Employment, Division of Workers' Compensation
- Cervical and Thoracic spine disorders (2011) American College of Occupational and Environmental Medicine

The committee's cover with conditions determination is consistent with these guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on cervical artificial disc replacement for public comment; followed by consideration for final approval at the next public meeting.

6. Meeting adjourned.