Washington State Health Care Authority

Health Technology Clinical Committee

Date: May 15, 2020
Time: 8:00 a.m. – 4:00 p.m.
Location: Webinar
Adopted: June 12, 2020

Meeting materials and transcript are available on the **HTA website**.

HTCC Minutes

Members present: John Bramhall, MD, PhD, Janna Friedly, MD; Chris Hearne, BSN, DNP, MPH; Conor Kleweno, MD; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Edward Novotny, MD; Jay Rubinstein, MD, PhD

HTCC Formal Action

1. **Call to order:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, a high-level overview of the HTA program, how to participate in the HTCC process, and upcoming topics.
3. **Previous meeting business:**

   January 17, 2020 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Nine committee members approved the January 17, 2020 meeting minutes. One member abstained.

   Final coverage determination on whole exome sequencing (WES): Chair referred members to the draft findings and decision and called for discussion. The HTA program received no comments in response to the posted HTCC draft findings and decision on WES. Motion made and seconded to accept the findings and decision, as written.

   Action: Nine committee members voted to approve the WES findings and decision. One committee member abstained.

   Final coverage determination on cell-free DNA prenatal screening for chromosomal aneuploidies (cfDNA): Chair referred members to the draft findings and decision and called for discussion. The HTA program received three public comments in response to the posted HTCC draft findings and decision on cfDNA. All three comments were in support of the HTCC determination. Motion made and seconded to accept the findings and decision, as written.

   Action: Nine committee members voted to approve the cfDNA findings and decision. One committee member abstained.

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4. Non-invasive, non-pharmacologic treatments for tinnitus

Clinical expert: The chair introduced Jay T. Rubinstein, MD, PhD, Virginia Merrill Bloedel Professor of Otolaryngology and Bioengineering; Director, Bloedel Hearing Research Center, University of Washington.

Agency utilization and outcomes: Judy Zerzan, MD, MPH, Clinical Quality Care Transformation, Health Care Authority, presented the state agency perspective on non-invasive, non-pharmacologic treatments for tinnitus. Find the full presentation published with the May 15, 2020, meeting materials.

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

- Jana Wiley, RN, LAC, Olympia WA
- Jianfeng Yang, L.Ac., M.Ac., OMD, Eastern Medicine Practitioner

Vendor report/HTCC question and answers: Leila Kahwati, MD, MPH, Research Triangle Institute (RTI) - University of North Carolina Evidence-based Practice Center, presented the evidence review for non-invasive, non-pharmacologic treatments for tinnitus. Find the full report published with the May 15, 2020, 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 decided that the current evidence on non-invasive, non-pharmacologic treatment of tinnitus is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of non-invasive, non-pharmacologic treatments for treatment of tinnitus. 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 cover cognitive behavioral therapy for treatment of tinnitus. The committee voted to not cover sound therapies including masking devices, repetitive transcranial magnetic stimulation and tinnitus specific therapies for the treatment of tinnitus.

	Not covered	Covered under certain conditions	Covered unconditionally
Cognitive behavioral therapy	0	0	10
Sound therapies including masking devices	10	0	0
Repetitive transcranial magnetic stimulation	10	0	0
Tinnitus specific therapies	9	1	0

Discussion

The committee reviewed and discussed the available studies for use of non-invasive, non-pharmacologic therapies for treatment of tinnitus. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion

points. A majority of committee members found the evidence sufficient to determine that use of cognitive behavioral therapy for the treatment of tinnitus is safe and efficacious, but unproven for cost-effectiveness. The committee found the evidence is insufficient to make a conclusion about whether repetitive transcranial magnetic stimulation, sound therapies and tinnitus-specific therapies are safe, effective and cost-effective for the treatment of tinnitus.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is no Medicare national or local coverage determination for the tinnitus treatments considered in this review.

Six evidence based clinical guidelines were identified for this review. The committee discussed guidelines from the following organizations related to the treatment of tinnitus:

- National Institutes for Health and Care Excellence (NICE) Guideline: Tinnitus assessment and management, 2020
- A multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment, 2019
- Association of the Scientific Medical Societies in Germany Guideline 01 7/064: Chronic Tinnitus, 2015
- American Academy of Otolaryngology-Head and Neck Surgery Clinical Practice Guideline: Tinnitus, 2014
- International Federation of Clinical Neurophysiology: Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation, 2014
- VA/DoD Clinical Practice Guidelines: Management of Concussion-mild Traumatic Brain Injury, 2016

The committee's coverage determination is consistent with the identified guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on the use of non-invasive, non-pharmacologic treatments for tinnitus for public comment to be followed by consideration for final approval at the next public meeting.

5. Vagal nerve stimulation for epilepsy and depression

Clinical expert: The chair introduced Edward J. Novotny, MD, Director, Director Epilepsy Program, Seattle Children's Hospital; Alvord, Gerlich and Rhodes Family Endowed Chair in Pediatric Epilepsy, University of Washington School of Medicine.

Agency utilization and outcomes: Emily Transue, MD, MHA, Clinical Quality Care Transformation, Health Care Authority, presented the state agency perspective on vagal nerve stimulation for epilepsy and depression. Find the full presentation published with the May 15, 2020, meeting materials.

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

- Gwinn Ryder, MD, Center for Neurologic Restoration, Swedish Neuroscience Institute
- Cathy Hill, American Association of Neurological Surgeons/ Congress of Neurological Surgeons, American Society for Stereotactic and Functional Neurosurgery Washington State Association of Neurological Surgeons
- Rebecca M. Allen, MD, MPH, Washington State Psychiatric Association
- Joshua Bess, MD
- David L. Dunner, MD, Director, Center for Anxiety and Depression
- Lorenzo Dicarlo, MD, LivaNova
- Scott Aaronson, MD
- Charles Conway, MD

Vendor report/HTCC question and answers: Beth Shaw, BSc, MSc, Oregon Health Sciences University, Center for Evidence-based Policy, presented the evidence review for vagal nerve stimulation for epilepsy and depression. Find the full report published with the May 15, 2020, 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 decided that the current evidence on vagal nerve stimulation for epilepsy and depression is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for the use of vagal nerve stimulation for the treatment of epilepsy and depression. 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 cover with conditions vagal nerve stimulation for the treatment of epilepsy. The committee voted to not cover vagal nerve stimulation treatment of depression, and to not cover transcutaneous vagal nerve stimulation for epilepsy or depression.

	Not covered	Covered under certain conditions	Covered unconditionally
Vagal nerve stimulation for epilepsy	0	10	0
Vagal nerve stimulation for depression	7	3	0
Transcutaneous vagal nerve stimulation	10	0	0

Discussion

The committee reviewed and discussed the available studies for use of vagal nerve stimulation for treatment of epilepsy and depression. Details of study design, inclusion criteria, outcomes and other

factors affecting study quality were discussed. A clinical expert member provided detailed insight and discussion points.

A majority of committee members found the evidence sufficient to determine that use of vagal nerve stimulation for the treatment of epilepsy in adults and children is safe and efficacious, but unproven for cost-effectiveness. All committee members found vagal nerve stimulation for epilepsy to be more effective in at least some cases, than comparators.

For treatment of depression the committee discussed details of the available clinical trial data. Half of the committee found the evidence insufficient to conclude the treatment to be safe, while the other half of the committee was split between concluding the evidence demonstrated it to be less safe or safer in some, than comparators. The majority of the committee found the evidence to be insufficient to make a conclusion related to effectiveness, and all committee members found insufficient evidence related to cost-effectiveness.

The committee unanimously found the evidence to be insufficient to conclude whether transcranial vagal nerve stimulation is safe, efficacious or cost-effective.

Limitations

N/A

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). There is one Medicare national coverage decision on the use of VNS. The committee also reviewed the new criteria for the NCD under development for VNS in depression. The committee determination is not consistent with the Medicare determination of coverage for depression only if in a clinical trial based on the committee's consideration of the most recent evidence. The committee acknowledged the state programs may consider coverage for individuals when in the context of a clinical trial.

Six evidence based clinical guidelines related to VNS or tVNS for epilepsy were identified for this review. The committee discussed guidelines from the following organizations related to the treatment of epilepsy:

- National Institutes for Health and Care Excellence (NICE) Guideline: Epilepsies: diagnosis and management, 2012
- Scottish Intercollegiate Guidelines Network (SIGN), diagnosis and management of epilepsy in adults, 2015
- Task Force Report for the ILAE Commission of Pediatrics, Management of Infantile Seizures, 2015
- Australian Government Medical Services Advisory Committee (MSAC), VNS for refractory epilepsy, 2016
- Epilepsy Implementation Task Force, management of medically- refractory epilepsy in adults and children who are not candidates for epilepsy surgery, 2016
- Wirrel et al. on behalf of a North American Consensus Panel, Diagnosis and management of Dravet syndrome, 2017

Five evidence-based clinical guidelines related to VNS or tVNS for depression were identified for this review. The committee discussed guidelines from the following organizations related to the treatment of depression:

- Working Group of the Clinical Practice Guideline on the Management of Depression in Adults, management of depression in adults, 2014
- Canadian Network for Mood and Anxiety Treatments, neurostimulation in the management of major depressive disorder in adults, 2016
- Department of Veterans Affairs, Department of Defense, management of major depressive disorder, 2016
- Royal Australian and New Zealand College of Psychiatrists, Management of mood disorders, 2015
- Australian Government Medical Services Advisory Committee (MSAC), VNS for chronic major depressive episodes, 2018

The committee's coverage determination is consistent with the identified guidelines.

The committee chair directed HTA staff to prepare a findings and decision document on the use of vagal nerve stimulation for epilepsy and depression for public comment to be followed by consideration for final approval at the next public meeting.

6. Meeting adjourned