

**Health Technology Clinical Committee
Findings and Decision**

Topic: Vagal nerve stimulation for epilepsy and depression
Meeting Date: May 15, 2020
Final Adoption: July 10, 2020

Meeting materials and transcript are available on the [HTA website](#).

Number and coverage topic:

20200515B – Vagal nerve stimulation for epilepsy and depression

HTCC coverage determination:

Vagal nerve stimulation for epilepsy is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

Vagal nerve stimulation for treatment-resistant depression is **not a covered benefit**.

Transcutaneous vagal nerve stimulation for epilepsy or depression is **not a covered benefit**.

HTCC reimbursement determination:

Limitations of coverage:

Vagal nerve stimulation for epilepsy is covered for adults and children (age 4 and older) when all of the following conditions are met:

- Seizure disorder is refractory to medical treatment, defined as adequate trials of at least 3 appropriate but different anti-epileptic medications.
- Surgical treatment is not recommended or has failed.

Non-covered indicators*:

- Vagal nerve stimulation for the treatment of depression
- Transcutaneous vagal nerve stimulation

*The scope of this determination does not include or apply to support of previously implanted VNS devices.

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

Final

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.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.