

June 23, 2023 Meeting Materials

Health Technology Clinical Committee

[Previous meeting business](#)

Contents

- Meeting minutes: May 19, 2023
- Timeline, Overview and Comments – Transcranial Magnetic Stimulation (TMS)
- HTCC instructions for final approval of coverage decision
- Draft findings and decision - TMS

Health Technology Clinical Committee

Date: May 19, 2023
Time: 8:00 a.m. – 3:00 p.m.
Location: Webinar
Adopted: Pending

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

HTCC Minutes

Members present: Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Christoph Lee, MD, MS; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD

Clinical expert: Simon Lo, MD

HTCC Formal Action

- Welcome and Chair remarks:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
- HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines, and an overview of the HTA program.
- Previous meeting business:**

March 17, 2023 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

Action: Six committee members approved the March 17, 2023 meeting minutes.

Vote on transcranial magnetic stimulation findings and decision:

Action: Five committee members voted on draft TMS findings and decision, which was below quorum and will be voted on again at a future meeting.

- Stereotactic body radiation therapy**

Washington State agency utilization and outcomes: Sophie Miller, MD, MPH, Medical Officer for Medicaid, Health Care Authority, presented the state agency perspective on stereotactic body radiation therapy. Find the full presentation published with the [May 19 meeting materials](#).

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

- Robert Meier, MD – Radiation Oncology Medical Director; Providence Swedish Radiosurgery Center; Seattle, WA
- Christopher Loisel, MD – Executive Medical Director; Providence Swedish Radiosurgery Center; Seattle, WA

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- Edward Kim, MD – Associate Professor; University of Washington; Seattle, WA
- Smith ‘Jim’ Apisarnthanarax, MD – Professor; University of Washington; Seattle, WA

Vendor report/HTCC questions and answers: Beth Shaw, MSc, Center for Evidence Based Policy, presented the evidence review for stereotactic body radiation therapy. The full presentation is published with the [May 19 meeting materials](#).

HTCC discussion and action:

Discussion

The committee reviewed and discussed the available studies for use of SBRT for prostate, lung, pancreatic adenocarcinoma, liver, oligometastatic, kidney, adrenal, head and neck, and bone cancers. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed. During discussion, the committee considered the evidence, public comment and expert input, and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Conditions for coverage were discussed and a draft was started, but not completed by the time the meeting was adjourned.

Action

The committee chair directed HTA staff to establish a follow up meeting to finalize discussion on SBRT to produce a draft findings and decision.

5. Meeting adjourned

Transcranial magnetic stimulation for treatment of selected conditions

Draft findings and decision
Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Proposed Topics published	March 2022	
Public comments		-
Selected technologies published	March 31	
Public comments	March 31 to May 1, 2022	31
Draft key questions published	July 8, 2022	
Public comments	July 8 to July 22, 2022	15
Final key questions published	August 23, 2022	
Draft report published	January 5, 2023	
Public comments	January 5 to February 6, 2023	33
Final report published	February 21, 2022	
Public meeting	March 17, 2023	
Draft findings & decision published	March 31, 2023	
Public comments	March 31 to April 14, 2023	14

Overview

Category	Comment Period	
	March 31 to April 14, 2023	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	2	0
Professional society & advocacy organization	0	0
Total	2	0

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Sarah Robilotta	Regence BlueCrossBlueSheild	No
<input type="checkbox"/>	2. Tawnya Christiansen LuAnn Chen	Community Health Plan of Washington	No
<input type="checkbox"/>	3.		
<input type="checkbox"/>	4.		
<input type="checkbox"/>	5.		

Hamann, Valerie (HCA)

From: Robilotta, Sarah [REDACTED]
Sent: Wednesday, April 12, 2023 4:59 PM
To: HCA ST Health Tech Assessment Prog
Subject: RE: Public comment open on HTCC draft findings and decision

External Email

Hello,
I work for Regence BCBS and on behalf of the leadership team, I would like to provide the following feedback:
Generally industry standards for authorizing TMS units/sessions is 34-36 sessions of 90868. Most provider protocols that we are familiar with do 36 sessions of 90868 for TMS.

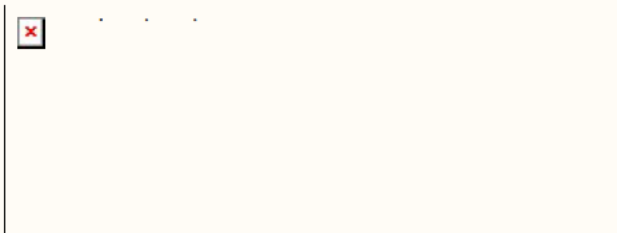
Thank you

Sarah Robilotta, LMHC
Supervisor, Behavioral Health Utilization Management
Regence Blue Cross Blue Shield
[REDACTED]

From: WA - Health Technology Assessment <shtap@public.govdelivery.com>
Sent: Friday, March 31, 2023 8:11 AM
To: Joyce, Audrey <Audrey.Joyce@regence.com>
Subject: Public comment open on HTCC draft findings and decision

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March 31, 2023

Public comment open on HTCC draft findings and decision.

The Health Technology Assessment (HTA) program will accept public comment on the HTCC [draft findings and decision](#) for transcranial magnetic stimulation (TMS).

Public comments on the draft findings will be accepted until close of business, April 14, 2023.

Submit all comments to shtap@hca.wa.gov.

About the Health Care Authority (HCA)

The Washington State Health Care Authority (HCA) is committed to whole-person care, integrating physical health and behavioral health services for better results and healthier residents.

HCA purchases health care for more than 2.5 million Washington residents through Apple Health (Medicaid), the Public Employees Benefits Board (PEBB) Program, the School Employees Benefits Board (SEBB) Program, and the COFA Islander Health Care Program. As the largest health care purchaser in the state, we lead the effort to transform health care, helping ensure Washington residents have access to better health and better care at a lower cost.

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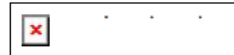
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HTCC final approval of coverage decision

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.

**Health Technology Clinical Committee
DRAFT Findings and Decision**

Topic: Transcranial Magnetic Stimulation (TMS)
Meeting date: March 17, 2023
Final adoption: Pending

Number and coverage topic:

20230317A – Transcranial Magnetic Stimulation for the Treatment of Selected Conditions

HTCC coverage determination:

TMS for treatment resistant major depressive disorder (MDD) in adult patients (age 18 or older) is a **covered benefit with conditions**.

TMS for treatment of obsessive-compulsive disorder (OCD), generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD), smoking cessation, and substance use disorder (SUD) are **not covered**.

HTCC reimbursement determination:

Limitations of coverage:

Initial treatment (up to 30 treatment sessions) is covered when ALL of the following criteria are met:

1. Failure of at least 2 different antidepressant medications from at least 2 separate classes at maximum tolerated dose for 4-12 weeks in separate trials; and
2. TMS is administered according to an FDA-cleared protocol.

Repeat TMS for MDD (up to 30 treatment sessions):

1. All of the above criteria have been met, and
2. Individual has shown evidence of 30% or more improvement, or a minimally clinically important difference, on a validated scale for depression, with most recent TMS treatment, and
3. Improvement in symptoms is maintained for at least 6 weeks.

Notes:

- Concurrent psychotherapy and/or antidepressant medication treatment is allowable as appropriate.
- Determination does not apply to age 17 and younger.

Related documents:

- [Final key questions](#)
- [Final evidence report](#)
- [Meeting materials and transcript](#)

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School Employees Health Plan	1-800-200-1004

Draft

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 discussed and voted separately on the evidence for the use of TMS for MDD, OCD, GAD, PTSD, smoking cessation, and SUD. The committee decided that the current evidence on TMS for MDD is sufficient to determine coverage with conditions. The committee considered the evidence, public comment and expert input, 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 TMS for MDD. Separately, the committee voted not to cover TMS for OCD, GAD, PTSD, smoking cessation, and SUD.

	Not covered	Covered under certain conditions	Covered unconditionally
TMS for MDD	0	9	0
TMS for OCD	9	0	0
TMS for GAD	9	0	0
TMS for PTSD	9	0	0
TMS for smoking cessation	9	0	0
TMS for SUD	9	0	0

Discussion

The committee reviewed and discussed the available studies for use of TMS for MDD, OCD, GAD, PTSD, smoking cessation, and SUD. Conditions for coverage were discussed, drafted, and voted on. All committee members present supported the conditions of coverage of TMS for MDD. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

TMS for treatment resistant **Major Depression Disorder (MDD)** in adult patients (age 18 or older) is a covered benefit with conditions:

Initial treatment (up to 30 treatment sessions) is covered when ALL of the following criteria are met:

1. Failure of at least 2 different antidepressant medications from at least 2 separate classes at maximum tolerated dose for 4-12 weeks in separate trials; and
2. TMS is administered according to an FDA-cleared protocol.

Repeat TMS for MDD (up to 30 treatment sessions):

1. All of the above criteria have been met, and

2. Individual has shown evidence of 30% or more improvement, or a minimally clinically important difference, on a validated scale for depression, with most recent TMS treatment, and
3. Improvement in symptoms is maintained for at least 6 weeks.

Notes:

Concurrent psychotherapy and/or antidepressant medication treatment is allowable as appropriate. Determination does not apply to age 17 and younger.

TMS is not covered for any age group for the treatment of other behavioral health disorders, including:

- Obsessive-compulsive disorder (OCD);
- Generalized anxiety disorder (GAD);
- Post-traumatic stress disorder (PTSD);
- Smoking cessation; and
- Substance use disorder (SUD)

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is no NCD for transcranial magnetic stimulation.

The committee discussed clinical guidelines identified from the following organizations:

- Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation (rTMS) (European Expert Panel) (2020)
- French Recommendations from experts, the French Association for Biological Psychiatry and Neuropsychopharmacology and the foundation FondaMental *Clinical guidelines for the management of treatment-resistant depression* (2019)
- National Network of Depression Centers rTMS Task Group and the American Psychiatric Association Council on Research Task Force on Novel Biomarkers and Treatments *Consensus Recommendations for the Clinical Application of Repetitive Transcranial Magnetic Stimulation in the Treatment of Depression* (2018)
- Canadian Network for Mood and Anxiety Treatments (CANMAT) *2016 Clinical Guidelines for the Management of Adults with Major Depressive Disorder* (2016)
- National Institute of Health and Care Excellence (NICE) *Repetitive transcranial magnetic stimulation for depression* (2015)
- National Institute of Health and Care Excellence (NICE) *Repetitive transcranial magnetic stimulation for obsessive-compulsive disorder* (2020)
- European Expert Panel *Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation (rTMS)* (2020)
- Canadian Anxiety Guidelines Initiative Group *Canadian clinical practice guidelines for the management of anxiety, posttraumatic stress and obsessive-compulsive disorders* (2014)

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on use of transcranial magnetic stimulation for the treatment of selected conditions for public comment to be followed by consideration for final approval at the next committee 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 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.