Washington State Health Care Authority

May 19, 2023 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

Washington State Health Care Authority

Health Technology Clinical Committee

Date: March 17, 2023
Time: 8:00 a.m. – 2:00 p.m.
Location: Webinar
Adopted: Pending

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

HTCC Minutes

Members present: John Bramhall, MD, PhD; Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Conor Kleweno, MD; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD
Clinical expert: Tuesday Burns, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** 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, and an overview of the HTA program.
3. **Previous meeting business:**

   Vote on meeting location

   Action: Seven committee members voted in favor of continuing meetings virtually.

   January 27, 2023 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Eight committee members approved the January 27, 2023 meeting minutes.
4. **Transcranial Magnetic Stimulation for Treatment of Selected Conditions**

   Washington State agency utilization and outcomes: Gary Franklin, MD, MPH, Medical Director, Labor and Industries, presented the state agency perspective on Transcranial Magnetic Stimulation (TMS). Find the full presentation published with the March 17 meeting materials.

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

   - Sina Shah-Hosseini, MD – Attending physician; Seattle Children's Hospital; Seattle, WA

   Vendor report/HTCC questions and answers: Shivani Reddy, MD, MSc, presented the evidence review for Transcranial Magnetic Stimulation for Treatment of Selected Conditions. The full presentation is published with the March 17 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 transcranial magnetic stimulation for treatment of selected conditions was sufficient to make a determination. The committee discussed and voted separately on the evidence for the use of TMS for major depressive disorder (MDD), obsessive compulsive disorder (OCD), generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD), smoking cessation, and substance use disorder (SUD). 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 in attendance supported the conditions of coverage for TMS. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed.

Committee's draft determination

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

Non-covered indicators

TMS is **not covered** for:

- OCD
- GAD
- PTSD
- Smoking cessation
- 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.

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

5. **Meeting adjourned**

Washington State Health Care Authority

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
☐ 1.	Sarah Robilotta	Regence BlueCrossBlueSheild	No
☐ 2.	Tawnya Christiansen LuAnn Chen	Community Health Plan of Washington	No
☐ 3.			
☐ 4.			
☐ 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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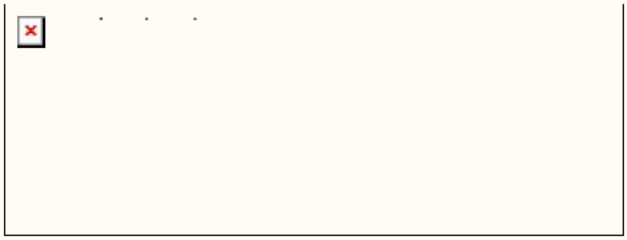

March 31, 2023

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.

Please do not reply directly to this message. For more information, visit the HCA website, where you'll also find contact information.

Disclosure notice

All messages we send via GovDelivery are subject to public disclosure, as are the names and email addresses of those who sign up for email notifications.

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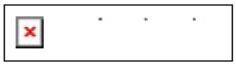

Ensure a sustainable future - only print when necessary.

Hamann, Valerie (HCA)

From: Tawnya Christiansen [redacted]
Sent: Friday, April 7, 2023 9:46 AM
To: HCA ST Health Tech Assessment Prog
Cc: Golob, Melanie (HCA); LuAnn Chen
Subject: Comment on HTCC draft findings/decision TMS

External Email

Hello, I have the following thoughts on the draft:

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 Is "failure" specifically defined? In our current MCO policy it is defined as failure to achieve **50% reduction** in symptoms in accordance with objective measures including but not limited to GDS, PHQ-9, BDI, or HAM-D. 50% reduction is a standard threshold for treatment "response" for depression. It seems that if the criteria for repeat TMS specify a symptom improvement threshold it would make sense to also do so in the initial criteria for approval. And it might be generally helpful to specify some validated measures here.
2. 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 – This appears to set the threshold for repeat TMS lower than the threshold for initial TMS. It would be helpful to perhaps set this at the threshold of 50% improvement in keeping with standards for "response", and to eliminate or more clearly define what is meant by a "minimally clinically important difference" in these criteria.
3. Improvement in symptoms is maintained for at least 6 weeks.

Related to both initial and repeat criteria: Is severity of depression incorporated into the definition of "treatment resistant depression"? That is, is this limited to moderate and higher severity?

Thank you for considering,
Tawnya

Tawnya Christiansen, M.D. Pronoun (she/her/hers)
Behavioral Health Medical Director
[redacted]

COMMUNITY HEALTH PLAN
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The power of community

Serving Washington communities for over 25 years.
CHPW acknowledges our work is on ***tribal lands***.

Washington State Health Care Authority

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.

Washington State Health Care Authority

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

Washington State Medicaid	1-800-562-3022

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)
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- 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.