

Health Technology Clinical Committee FINAL Findings and Decision

Topic:Transcranial Magnetic Stimulation (TMS)Meeting date:March 17, 2023Final adoption:June 23, 2023

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), posttraumatic 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,
- 2. Improvement in symptoms is maintained for at least 6 weeks following initial treatment session, and
- 3. Individual has shown evidence of 30% or more improvement on the Hamilton Depression Rating Scale, **OR** a minimally clinically important difference on a validated scale for depression, with most recent TMS treatment.

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
- <u>Meeting materials and transcript</u>

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.

Covered under Covered Not covered unconditionally certain conditions 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 9 0 TMS for SUD 0

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.

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
- 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.