VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Transcranial Magnetic Stimulation (TMS)

CDI Number: 00026

Original Effective Date: January 1, 2025

Last Review Date: January 1, 2025

I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for Transcranial Magnetic Stimulation

Transcranial magnetic stimulation (TMS) is indicated for the treatment of major depressive disorder (MDD) and obsessive-compulsive disorder (OCD) and is considered **medically necessary** when **ALL** the following criteria are met:

- Confirmed diagnosis of MDD (single or recurrent episode) or OCD by a qualified mental health professional
- At least a moderate level of depression or OCD documented using professional clinical judgement or an evidence-based rating scale
- Meet at least **ONE** of the following:
    - Failed response to at least one trial of a generally accepted dose of a standard psychopharmacologic agent meant to treat MDD administered in the current episode or OCD
        - The trial length was at least six weeks
    - Inability to tolerate psychopharmacologic agents meant to treat MDD or OCD due to intolerable side effects and those side effects are not expected to diminish or resolve with continued administration of the medication
    - Documented history of successful response to TMS in a previous depressive episode, as evidenced by at least 50% improvement on a standard rating scale for depression symptoms
    - Documentation that TMS treatment is an alternative to a more invasive treatment option for MDD, such as electroconvulsive therapy, ketamine, and/or esketamine

- The TMS order is written by a psychiatrist (MD or DO) or psychiatric nurse practitioner (NP) who has examined the individual and has experience in administering TMS

b. Limitations/Exclusions

Due to insufficient evidence of efficacy and safety, TMS is **not indicated** for the treatment of the following as a **primary** indication but may be administered if presenting as comorbid with MDD or OCD:

- Chronic pain
- Post traumatic stress disorder (PTSD)
- Tourette syndrome
- Traumatic brain injury
- Various other movement disorders

Conditions/indications for which TMS is **not medically necessary** include, but are not limited to, the following:

- Bipolar I disorder
- Major depression with psychotic features
- Schizophrenia
- Schizoaffective disorder

For all conditions/indications not listed in section II.a. of this document, TMS is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Treatment Limitations

A course of TMS is considered medically necessary for a maximum of 36 sessions, in alignment with the following:

- Delivered at a rate consistent with FDA clearance for the device being used
- The SAINT (Stanford Accelerated Intelligent Neuromodulation Treatment) protocol is only considered medically necessary when using the FDA approved SAINT neuromodulation system by Magnus

d. Description of Treatment

Transcranial magnetic stimulation (TMS) is a noninvasive way to stimulate the cerebral cortex and should only be administered using a device that is cleared for use by the Food and Drug Administration (FDA). During the procedure, a magnetic coil is held over the person's head and an electric current is delivered to the coil by a stimulator. This current flows through loops in the coil, generating a magnetic field. The magnetic field passes through the skull

to the brain, where it creates an electrical stimulation of the brain. The stimulator applies a specific pattern, or waveform, of current to the coil, which is replicated in the brain. Different coil types produce different magnetic field patterns and using more focal points can obtain a deeper magnetic field to stimulate deeper cortical layers. Repetitive, or therapeutic transcranial stimulation refers to applying a rapid series of magnetic pulses one after the other.

A typical course of TMS treatments is delivered daily for up to 30 sessions followed by a taper of up to 6 sessions. During the TMS procedure, the patient sits comfortably in a chair, usually with a headrest for support. A doctor or medical technician positions the coil over the patient's head and programs the appropriate pulse waveform into the device. The sensation is not typically painful and may feel like tapping on the head, mild shocks, or muscle twitches. The sensation goes away as soon as the TMS is stopped. A single session of TMS can last up to 60 minutes, which includes treatment set up.

Common side-effects of TMS include headaches, scalp discomfort at the stimulation site, tingling, facial spasms or twitching, lightheadedness, and sleep disruption. Rarely, fainting or seizures may occur during stimulation. Other rare side effects include: a transient state of confusion related to disruptions in cognition, hearing, or vision. Side effects are generally mild to moderate and improve shortly after the session has ended. The presence and intensity of side effects should decrease over time as the patient undergoes more sessions. The magnitude of pulses or coil placement can be adjusted to minimize side effects if necessary.

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information: Transcranial Magnetic Stimulation for Depression

Depression is the leading cause of disability, a major contributor to suicide, and is associated with poor medical outcomes among people ages 15 to 44 in the United States. While depression can occur at any age, it most often initially appears during the late teens to mid-20s. Studies show women are more likely than men to experience depression, with some research indicating one-third of women will experience a major depressive episode in their lifetime. Depression can also be hereditary, with a higher incidence among

those with first-degree relatives (parents/children/siblings) who have depression.

Depression is a mood disorder characterized by persistent feelings of sadness, loss of interest in life, and other symptoms. While it's normal to feel temporarily sad, clinical depression is different. People experiencing normal sadness may refer to themselves as depressed, true clinical depression involves more intense and persistent symptoms that may impact daily functioning.

In major depressive disorder (MDD) the persistently low or depressed mood and loss of interest in activities lasts several weeks or months. A person may have multiple episodes of major depression over time.

Diagnosing Depression

To diagnose depression, a health professional will conduct a thorough diagnostic evaluation, including an interview and a physical examination. In some cases, a blood test may be ordered to rule out potential medical causes like thyroid disorders or vitamin deficiencies – treating these underlying issues may alleviate the depressive symptoms. The evaluation aims to identify specific symptoms and explore the patient's medical and family history as well as cultural and environmental factors with the goal of arriving at a diagnosis and planning a course of action.

Treatment for MDD

There are many different treatment options for MDD, however, first line approaches such as antidepressants and psychotherapy do not work for everyone. Approximately two-thirds of people diagnosed with depression fail to achieve adequate relief from their first antidepressant trial.

Electroconvulsive therapy (ECT) is considered a gold standard in treatment for people with MDD that do not respond to first line medication treatments. However, ECT can be difficult for some to tolerate due to side effects on memory and cognition. For those who find ECT difficult, or those who choose not to participate in ECT, transcranial magnetic stimulation (TMS) is a less invasive alternative.

Transcranial magnetic stimulation (TMS) is a noninvasive technique using a device to deliver brief magnetic pulses to the brain for the treatment of MDD. These pulses generate electrical currents in the brain tissue, activating neurons which release neurotransmitters like serotonin, norepinephrine, and dopamine. TMS helps restore brain function.

b. Background Information: Transcranial Magnetic Stimulation for Obsessive-Compulsive Disorder

Obsessive-compulsive disorder (OCD) affects 2-3% of people in the United States and women are more likely to experience OCD than men. While OCD can occur at any age, it most often begins in childhood, adolescence, or early adulthood.

Obsessive-compulsive disorder (OCD) is a disorder characterized by recurring, unwanted thoughts, ideas, or sensations (obsessions). To alleviate these thoughts or ideas a person is driven to do something repetitively (compulsions). The repetitive behaviors, such as hand washing/cleaning, checking on things, and mental acts like (counting) or other activities, can significantly interfere with a person's daily activities and social interactions.

Diagnosing OCD

To diagnose OCD, a health professional will conduct a thorough diagnostic evaluation, including an interview and a physical examination. In some cases, other tests may be ordered to rule out other potential causes of the presenting symptoms. The evaluation focuses on exploring medical and family history and identifying specific symptoms of obsessional thoughts and/or compulsions that are time-consuming (more than one hour a day), cause significant distress, and impair work or social functioning.

Treatment for OCD

The initial treatments for OCD are cognitive behavioral therapy, medications, or both (therapy and medications). If OCD symptoms do not improve with these treatments, TMS may be administered. TMS targets specific areas of the brain that are associated with OCD.

Patients with depression and OCD who receive appropriate treatment commonly experience increased quality of life and improved functioning. Proper diagnosis and treatment are key to returning to optimal health.

c. Research, Clinical Trials, and Evidence Summaries

Studies support the use of TMS for the treatment of MDD and OCD. There is an ongoing need for evidence regarding the benefit of TMS maintenance therapy to control MDD and recurrence of future episodes.

Madore et al. (2021) developed a nationwide multisite TMS program modeled after positive control trials and naturalistic studies. The program provides evidence based TMS to Veterans with MDD while evaluating its safety and clinical effectiveness. Patients included had an MDD diagnosis, failed more than one antidepressant in the current depressive episode and had no

changes in other treatments (e.g., medication, psychotherapy, etc.) six weeks prior to stimulation. The majority of Veterans received high frequency stimulation, e.g., daily TMS delivered at 10 Hz to the left DLPFC at 120% of motor threshold for up to 30 sessions followed by a six-session taper. Symptoms were measured using the 9-item patient health questionnaire and PTSD checklist. Of the 770 Veterans who received at least one session, TMS was associated with clinically meaningful (Cohen's d>1.0) and statistically significant (all p<.001) reductions in MDD and PTSD. Among the Veterans who received an adequate number of treatments, 340 demonstrated a MDD response rate of 41.4% and a remission rate of 20%. Veterans with comorbid PTSD, demonstrated clinically meaningful reduction of 65.3% and 46.1% no longer met PTSD threshold criteria after TMS. In conclusion, this multisite, large-scale data supports the effectiveness and safety of TMS for Veterans with MDD and PTSD using standard clinical approaches.

Perera et al. (2016) developed treatment recommendations for TMS therapy for MDD. These clinical guidelines have been approved by the Clinical TMS Society. The authors systematically reviewed over 100 published TMS antidepressant therapy clinical trials. Twenty-three of these studies were assessed and graded on their strength of evidence using the Levels of Evidence framework published by the University of Oxford Centre for Evidence Based Medicine. The authors also summarized essentials for using TMS therapy in routine clinical practice settings collected from a survey given to The Clinical TMS Society attendees at its annual meeting on May 28th, 2015. In conclusion, it has been established that daily left prefrontal TMS has substantial evidence of efficacy and safety for treating the acute phase of depression in patients who are treatment resistant or intolerant.

Lefaucheur et al. (2020) conducted a review of ten clinical studies evaluating the efficacy of TMS for MDD when applied to left and right hemispheres of the brain. Four studies, consisting of a total of 237 patients, assessed the efficacy of high frequency left dorsolateral prefrontal cortex (DLFPC) in patients with MDD. Three of the four studies (156 patients) showed significant decreases of 40-58% in depression scores. The next group of three studies included a total of 276 patients. These groups examined deep high frequency, left DLFPC in patients with MDD. Two of the three studies (224 patients) showed reduced depression scores of 50% and higher rates of remission. The last group of three studies (148 patients) administered both left and right stimulation. Two of the three studies (92 patients) resulted in reduction in depression scores of 50% and a trend toward higher response rate at follow up. In conclusion, the authors report positive antidepressant results for left and right hemisphere TMS.

Carmi et al. (2019) conducted a double-blind sham-controlled study to evaluate the effects of deep transcranial stimulation (dTMS) on patients with obsessive compulsive disorder (OCD). A total of 99 patients diagnosed with OCD were randomly assigned to either high frequency (20 Hz) dTMS treatment or an identical sham procedure without actual stimulation. Each patient received daily treatment for six weeks. Clinical response to treatment was determined using the Yale-Brown Obsessive Compulsive Scale (YBOCS), and the primary efficacy endpoint was the change in score from baseline to posttreatment assessment. Patients receiving active dTMS showed a 6-point YBOCS score reduction, compared to a 3.3-point reduction for the sham treatment. At the one-month follow up, response rates were 45.2% for patients in the active treatment group and 17.8% in the sham group. In conclusion, high frequency dTMS significantly improved OCD symptoms and may be considered as a potential intervention for patients who do not respond adequately to pharmacological and psychological interventions.

d. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm

e. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

NCD Number	Name	Effective Date
None	N/A	N/A

LCD Number	Contractor	Original/Revision Effective Date
L33398	National Government Services, Inc	04/01/2023
L34869	Palmetto GBA	06/09/2022
L36469	CGS Administrators, LLC	06/06/2024
L37086	Noridian Healthcare Solutions, LLC	08/20/2023

LCD Number	Contractor	Original/Revision Effective Date
L34641	Wisconsin Physicians Service Insurance Corporation	04/25/2024
L34522	First Coast Service Options, Inc.	12/11/2022
L34998	Novitas Solutions, Inc.	12/11/2022

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

f. TRICARE Policy Manual

TRICARE Policy Manual 6010.63-M, Chapter 07, Section 3.7

Transcranial magnetic stimulation (TMS) also referred to as repetitive TMS (rTMS) for the treatment of MDD (CPT 90867, 90868, and 90869) is proven.

- Transcranial magnetic stimulation requires preauthorization to ensure beneficiary has failed to respond to a less intensive form of treatment or that a less intensive intervention is not more appropriate.

IV. Definitions

Term	Definition
Beck Depression Scale	A self-reported tool that measures characteristic attitudes and symptoms of depression
Dopamine	A neurotransmitter made in the brain that plays a role in memory, movement, motivation, mood, and attention
Double-Blind Sham-Controlled Study	A medical study which neither the participants or providers know who is receiving the treatment or a placebo
Dorsolateral Prefrontal Cortex	Portion of the brain associated with control functions such as task switching, prevention of interference, inhibition, planning, and working memory
Hamilton Depression Rating Scale	Clinician rated scale assessing depression
Hereditary	Determined by genetic factors and therefore able to be passed on from parents
Montgomery-Asberg Depression Rating Scale	Clinician rated scale assessing depression symptoms
Neurotransmitters	Chemicals in the brain that allow neurons to communicate with each other throughout the body
Norepinephrine	A neurotransmitter and a hormone that serves as a chemical messenger to help transmit nerve signals across nerve endings to another nerve cell, muscle cell or gland cell

Term	Definition
Pessimistic	Tending to see the worst aspect of things or believe the worst will happen
Serotonin	A neurotransmitter that carries messages between nerve cells in the brain throughout the body
Transcranial	Passing or performed through the skull
Transient Confusion	An episode of confusion that comes on suddenly in a person who is otherwise alert
Yale-Brown Obsessive Compulsive Scale	Rates the severity separately for both obsessions and compulsions of OCD according to the time occupied, degree of interference, subjective distress, internal resistance, and degree of control

V. References

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VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	