Coverage Guidance for Transcranial Magnetic Stimulation (TMS) for Major Depressive Disorder (MDD)

COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY

Introduction: Transcranial Magnetic Stimulation (TMS) is a non-invasive treatment that uses pulsed magnetic fields to induce an electric current in a localized region of the cerebral cortex. An electromagnetic coil placed on the scalp induces focal, patterned current in the brain that temporarily modulates cerebral cortical functioning. Stimulation parameters may be adjusted to alter the excitability of the targeted structures in specific cortical regions. TMS parameters include cranial location, stimulation frequency, pattern, duration, intensity and the state of the brain under the coil.

History/Regulatory: In October 2008, conventional repetitive TMS (TMS) was FDA cleared for the treatment of adults with major depressive disorder (MDD) who had one failed medication trial[1]. TMS has since been established as a treatment with an excellent safety profile. TMS is minimally invasive and does not require anesthesia, has no cognitive side effects, and is carried out in outpatient clinics. TMS can be administered with different coils and different protocols. In 2013 deep[2] and conventional[3] repetitive TMS (dTMS) were cleared for treatment resistant MDD, defined as having failed to respond to antidepressant medication, without a specific number of medication trials. In 2018 theta burst stimulation (iTBS) was cleared for MDD[4].

Major Depressive Disorder:
TMS is used for Major Depressive Disorder[5–8]. Other non-invasive treatment options for MDD include psychotherapy and pharmacotherapy. Psychotherapy for MDD is indicated in mild major depressive disorder and can be useful as an augmentation to treatment of moderate to severe major depressive disorder. Pharmacotherapy options include selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), heterocyclic agents, other FDA-approved antidepressants from other classes, monoamine oxidase inhibitors (MAOIs) and augmentation of these agents with drugs from different classes (antipsychotics/mood stabilizers/stimulants/lithium/ketamine). Electroconvulsive Therapy (ECT) is indicated for severe MDD, bipolar disorder, schizophrenia, catatonia, and acute suicidal ideation. ECT is a burdensome treatment for patients, requires general anesthesia for a seizure multiple times a week, and carries risks of both the anesthesia as well as the ECT itself, primarily cognitive impairment. This prevents patients from functioning independently through their treatment course. The only invasive treatment approved for MDD is vagal nerve stimulation.

INDICATIONS FOR COVERAGE

TMS for MDD should be considered medically necessary and should be covered when prescribed by a licensed psychiatrist trained in the use of TMS, when the patient meets the below criteria:

Initial Treatment Criteria:

Adults 18 years and older meeting the following criteria:

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1. (Required): A diagnosis of Moderate or Severe Major Depressive Disorder (MDD), single episode or recurrent as per DSM-5 criteria as documented by a clinical evaluation. The severity and current symptoms may be quantified using a standardized patient or clinician rating scale.

AND

2. One or more of the following:

- Failure of one (1) trial of a psychopharmacologic agent for depression of adequate dose and duration in the current depressive episode, ***or*** failure to respond to electroconvulsive therapy.
- Inability to tolerate a therapeutic dose of medications as evidenced by two (2) trials of psychopharmacologic agents for depression, with documented side effects (trials do not need to have been during the current depressive episode), ***or*** inability to tolerate electroconvulsive therapy, ***or*** patient declining a recommendation for ECT.
- History of response to repetitive TMS as demonstrated by 50% improvement in symptoms.
- A current or prior medical condition, or history indicating the use of additional antidepressant medication would be contraindicated.

The order for treatment (or retreatment) must be written by a psychiatrist (MD or DO) who has examined the patient, reviewed the record, and is prescribing an evidence-based TMS protocol on an FDA-cleared device the physician is trained to operate. A physician shall oversee the treatment, but does not have to personally administer the sessions nor be in the area. A prescribing or covering physician must be immediately reachable and interruptible in case of questions or problems during treatment.

CONTRAINDICATION

The only absolute contraindication to TMS is the presence of ferromagnetic metal in the head, such as a plate, screws, or an implanted magnetically sensitive medical device located less than or equal to 10 cm from the TMS coil[9].

UTILIZATION GUIDELINES

The treatment must be provided by a device cleared by the FDA for the purpose of TMS for depression, using an evidence-based protocol. It is expected that the services will be performed as indicated by current medical literature and standards of practice.

TMS for adolescents with MDD may be appropriate and should be considered on a case-by-case basis, if there is a high level of treatment resistance[10], and the patient meets all criteria for TMS other than age. These cases should be reviewed individually for medical necessity and considered for compassionate use.

TMS is reasonable and necessary for at least 36 visits. The initial authorization therefore includes 36 treatments to reflect usual practice. For patients who demonstrate a late response to TMS, subsequent treatment extensions in ten treatment increments are allowed based on clinical need. TMS response should be monitored by periodic outcome testing with appropriate standardized patient or clinician depression symptom measures.

If patients cannot come in five days a week, treatments may be administered at a lower frequency over a longer period of time[11].

Electroconvulsive Therapy (ECT) is not a pre-requisite for TMS authorization or coverage.

CODING

CPT/HCPCS Codes Group 1 Paragraph:

Group 1 Codes: CODE	DESCRIPTION
90867 x 1	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; INITIAL, INCLUDING CORTICAL MAPPING, MOTOR THRESHOLD DETERMINATION, DELIVERY AND MANAGEMENT
90868 (all other days)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT DELIVERY AND MANAGEMENT, PER SESSION
90869 (once weekly, and more frequently when clinically indicated such as a change of medication or if clinically indicated)	THERAPEUTIC REPETITIVE TRANSCRANIAL MAGNETIC STIMULATION (TMS) TREATMENT; SUBSEQUENT MOTOR THRESHOLD RE-DETERMINATION WITH DELIVERY AND MANAGEMENT

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