# Corporate Medical Policy

# Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

**File Name:** transcranial_magnetic_stimulation_tms
**Origination:** 10/2019
**Last Review:** 6/2024

## Description of Procedure or Service

Transcranial magnetic stimulation (TMS), introduced in 1985 as a new method of noninvasive stimulation of the brain, involves placement of a small coil over the scalp, passing a rapidly alternating current through the coil wire, which produces a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex. Transcranial magnetic stimulation was initially used to investigate nerve conduction (eg, TMS over the motor cortex will produce a contralateral muscular-evoked potential). The motor threshold, which is the minimum intensity of stimulation required to induce a motor response, is empirically determined for each person by localizing the site on the scalp for optimal stimulation of a hand muscle, then gradually increasing the intensity of stimulation. Interest in the use of TMS as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation. Imaging studies had shown a decrease in the activity of the left dorsolateral prefrontal cortex in depressed patients, and early studies suggested that high-frequency (eg, 5 to 10 Hz) TMS of the left dorsolateral prefrontal cortex had antidepressant effects. In contrast to electroconvulsive therapy (ECT), TMS does not require general anesthesia and does not generally induce a convulsion. Repetitive TMS (rTMS) is also being tested as a treatment for a variety of other psychiatric and neurologic disorders.

Conventional TMS delivers repeated electromagnetic pulses to induce prolonged modulation of neural activity, typically applied over the dorsolateral prefrontal cortex. High-frequency rTMS (usually ≥10 Hz) induces an increase in neural activity whereas low-frequency TMS (usually ≤1 Hz) has the opposite effect. If both procedures are performed in the same session, the intervention is described as bilateral rTMS.

A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation. Deep TMS employs an H-coil helmet design to encompass a broader surface area and stimulate deeper brain structures than conventional TMS. Theta burst stimulation is administered at lower intensities and shorter intervals than conventional rTMS.

### Regulatory Status

Devices for transcranial stimulation have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for diagnostic uses. A number of devices subsequently received the FDA clearance for the treatment of major depressive disorder in adults who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Indications were expanded to include treating pain associated with certain migraine headaches in 2013, and obsessive-compulsive disorder in 2018. US Food and Drug Administration (FDA) approves TMS device therapy for repeated daily use over 4–6 weeks (20–30 sessions).

Listed below are FDA approved TMS devices for depression and their manufacturers.

| Device | Manufacturer | Indication |
|---|---|---|
| Neurostar | Neuronetics | Major depressive disorder and obsessive-compulsive disorder |
| Brainsway Deep TMS System | Brainsway | Major depressive disorder and obsessive-compulsive disorder |
| Rapid Therapy System | Magstim | Major Depressive Disorder |
| Magvita | Tonica Elektronik | Major Depressive Disorder |
| Mag Vita TMS Therapy System w/Theta Burst Stimulation | Tonica Elektronik | Major Depressive Disorder |
| Neurosoft | TeleEMG | Major Depressive Disorder |
| Horizon | Magstim | Major Depressive Disorder |
| Nexstim | Nexstim | Major Depressive Disorder |
| Apollo | Mag & More | Major Depressive Disorder |
| Horizon TMS Therapy System (Theta Burst Protocol) | Magstim | Major Depressive Disorder |
| ALTMS Magnetic Stimulation Therapy System | REMED Co., Ltd | Major depressive disorder |
| Horizon 3.0 TMS Therapy System | Magstim | Major depressive disorder and obsessive-compulsive disorder |

**Related Policies:**
Vagus Nerve Stimulation
Tinnitus Treatment

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

## Policy

**BCBSNC will provide coverage for Transcranial Magnetic Stimulation (TMS) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

# Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

## When Transcranial Magnetic Stimulation (TMS) is covered

All types of repetitive transcranial magnetic stimulation (rTMS) of the brain may be considered medically necessary as a treatment of major depressive disorder in adults aged 18 years and older when **all** of the following conditions (1-4) have been met:

1. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms; and
2. Any one of the following (a, b, or c):
    a. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; or
    b. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; or
    c. Is a candidate for electroconvulsive therapy; further, electroconvulsive therapy would not be clinically superior to rTMS (eg, in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be used); and
3. Failure of a trial of a psychotherapy known to be effective in the treatment of major depressive disorder of an adequate frequency and duration, without significant improvement in depressive symptoms, as documented by standardized rating scales that reliably measure depressive symptoms; and
4. Device is FDA approved and utilized in accordance with the FDA labeled indication of major depressive disorder.

**Repeat rTMS (retreatment) of the brain may be considered medically necessary as a treatment of major depressive disorder in adults aged 18 years and older when all of the following have been met:**

- Initial criteria for rTMS treatment were met for previous depressive episode, and
- After initial rTMS treatment course, member achieved remission or at least a 50% reduction in depressive symptoms as measured by a standardized rating scale for depression, and
- Member is experiencing relapse or recurrence of a severe major depressive episode, and the recurrent episode is considered severe, as measured by a standardized rating scale for depression, and
- At least 3 months has lapsed since prior treatment with rTMS, and
- Retreatment is not requested as maintenance therapy or continuous therapy

**For initial/repeat therapy, the following may be considered medically necessary:**

- 9-week course of treatment
    - 1 unit of 90867
    - 36 units of 90868
        - 5 daily treatments over 6 weeks
        - Taper of twice weekly treatments over 3 weeks
    - Redetermination, 1 unit of 90869

**For extension of initial therapy, the following may be considered medically necessary:**

- 4-week course of treatment
    - 8 units of 90868
        - Twice weekly treatments over 4 weeks
    - Redetermination, 1 unit of 90869

## When Transcranial Magnetic Stimulation (TMS) is not covered

Repetitive TMS for major depressive disorder that does not meet the criteria listed above is considered investigational.

Continued treatment with rTMS of the brain as maintenance therapy is considered investigational

Repetitive TMS of the brain is considered investigational as a treatment of all other psychiatric and neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

Contraindications to repetitive TMS include:

a. Seizure Disorder or any history of seizure with increased risk of future seizure; or
b. Presence of acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
c. Neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system; or
d. Presence of an implanted magnetic-sensitive medical device located within 30 centimeters from the TMS magnetic coil or other implanted items including but not limited to a cochlear implant, implanted cardioverter defibrillator, pacemakers, vagus nerve stimulator or metal aneurysm clips or coils, staples, or stents.

## Policy Guidelines

Repetitive TMS includes, but is not limited to, the following protocols:

- Theta burst (iTBS)
- Accelerated
- Deep
- Surface or superficial
- Unilateral

**Definitions**

Acute initial treatment- most studies support that an initial trial of rTMS should last at least three to four weeks before determining whether it is beneficial. However, the number of treatments necessary is not standardized, and the definition of clinical benefit has varied across studies.

The evidence for the efficacy of initial therapy with TMS consists of three randomized, sham controlled trials, with an aggregate 703 patients. Two were industry sponsored (Neurostar, Brainsway) and one was sponsored by the National Institute of Mental Health (NIMH). Only the NIMH-sponsored trial focused on a clinical endpoint of remission, based on the Hamilton Rating Scale for Depression (HAMD24). In the Neuronetics and Brainsway trials, a meaningful improvement was defined by comparing the baseline to endpoint change on the Montgomery-Asberg Depression Rating Scale (MADRS) and/or HAM scales between the active and sham groups.

Extension of initial treatment for additional weeks is reasonable in patients who only achieve a partial response to initial therapy that has not plateaued and for those who have a prior history of late response to antidepressant medications (late response is defined as after 10 weeks).

The evidence for extension of initial treatment is from two observational studies (Avery et al 2008, McDonald et al 2011). In the McDonald study, patients who were part of a randomized, sham controlled trial of TMS were allowed to receive extension therapy if after three weeks of initial therapy they did not achieve remission (remission defined as a HAM-D score of $\leq 3$ or two consecutive weekly HAM-D scores less than 10), but who improved (improvement defined as having at least a 30% reduction in HAM-D score from baseline but without an absolute score meeting remission criteria). This group continued extended treatment for up to 3 additional weeks if they continued to show improvement (defined as at least a two point drop in the HAM-D per week). Remission occurred in 31 percent. In the Avery study, 73 patients who did not respond to daily rTMS for four to six weeks were

treated for six more weeks, and response (defined as improvement from baseline on a depression rating scale ≥50%) occurred in 26 percent.

Maintenance therapy: Maintenance TMS may be defined as a course that begins after the end of the initial therapy and is intended to prevent recurrence of a new episode. However, the frequency of sessions for maintenance TMS has not been standardized, and evidence is not available to support one specific maintenance schedule over another. Nor is it known for how long a patient should receive maintenance.

There is a lack of randomized trials to assess and define maintenance TMS therapy. The best evidence for maintenance consists of one small prospective trial (Philip, 2015) which enrolled 67 patients with treatment resistant depression who underwent 6 weeks of acute TMS and were randomized after 6 weeks to scheduled maintenance or observation if they responded to the six weeks of acute therapy. Forty-nine patients who met the response criteria (acute phase endpoint HAMD17 total score <15 and more than 25% improvement in total score HAMD17 compared to baseline) were randomized to a single TMS session scheduled monthly as maintenance or observation only, with 12 months follow-up. There was a longer time to relapse in the group that received the scheduled maintenance, but it did not reach statistical significance.

The remaining published evidence for maintenance therapy consists of small observational studies.

Depression Assessment Instruments

The Hamilton Rating Scale for Depression (HAM-D24) is a 17-item rating scale to determine the severity level of depression in a patient before, during, and after treatment. The total score ranges from 0 to 52, with the score corresponding to the following classifications:
• 0-7: No depression (normal)
• 8-16: Mild depression
• 17-23: Moderate depression
• ≥24: Severe depression

Montgomery-Asberg Depression Rating Scale (MADRS), an adaptation of the HAM-D, is a 10-item scale with each item rated on a 0-6-point scale. MADRS investigates the presence of affective, somatic, cognitive and behavioral symptoms of depression. MADRS has as a greater sensitivity to change in symptoms over time. The total score classifies the patient's level of severity of depression as normal or absent 0–6; mild 7–19; moderate 20–34; severe 35–60.

Patient Health Questionnaire 9 (PHQ-9) relies on patient self-report. There are nine questions based on the nine DSM-IV depression diagnostic criteria, and scores are based on frequency of symptoms. The possible range is 0-27, with minimal depression 0-4, mild 5-9, moderate 10-14, moderately severe 15-19, and severe 20-27.

Evidence summaries

For individuals who have TRD who receive TMS, the evidence includes a large number of sham-controlled randomized controlled trials (RCTs) and meta-analyses of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. Meta-analyses found improved response rates and rates of remission for conventional TMS and theta burst stimulation compared with sham TMS. Additionally, a head-to-head trial showed noninferiority of theta burst stimulation to conventional TMS, with no difference in the incidence of adverse events. Meta-analyses have concluded that the effect of TMS on average depression scores is smaller than the effect of electroconvulsive therapy (ECT) on TRD and that the mean improvement in depression scores with TMS did not reach the minimal clinically important difference; however, clinically meaningful improvements were noted in a subgroup of studies using higher frequency pulses. One potential area of benefit for TMS is in

accelerating or enhancing the response to antidepressant medications, and there is some evidence that TMS, when given in conjunction with the initiation of pharmacologic therapy, improves the response rate compared with pharmacologic therapy alone. The effect of TMS appears to be less robust when it is given in combination with a stable dose of antidepressant medication. Meta-analyses have also found that the efficacy of TMS decreases with longer follow-up, though some studies have reported a persistent response up to 6 months in some patients. There is limited evidence to compare the effects of these treatments on cognition, although the adverse events of TMS appear to be minimal. While meta-analyses have reported that the effect of TMS is smaller than the effect of ECT on TRD, because TMS does not require general anesthesia or induce seizures, some individuals may decline ECT so the balance of incremental benefits and harms associated with TMS may be reasonable compared with ECT. Based on the short-term benefit observed in RCTs and the lack of alternative treatments aside from ECT in patients with TRD, TMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have migraine headaches who receive TMS, the evidence includes a systematic review and a sham controlled RCT of 201 patients conducted for submission to the U.S. Food and Drug Administration (FDA) for clearance in 2013. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review found that rTMS reduced migraine pain intensity and frequency compared to sham; it was unclear whether patients were receiving background pharmacotherapy. The trial results were limited by the 46% dropout rate and the use of a post hoc analysis. No recent studies have been identified with these devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obsessive-compulsive disorder (OCD) who receive TMS, the evidence includes a number of small-to-moderate sized, sham-controlled, double-blind RCTs and meta-analyses of these studies. Relevant outcomes are symptoms, functional outcomes, and quality of life. A meta-analysis of 15 RCTs conducted in 2016 found a benefit of TMS on patient-reported OCD symptom severity at time points ranging from 2 to 6 weeks, but there was substantial variability in the stimulation parameters, including the cortical region that was stimulated and the frequency of stimulation. A meta-analysis conducted in 2021 included 26 RCTs. The primary analysis found a significant effect of rTMS compared to sham on OCD symptoms, but the effect seemed to last only until 4 weeks after the last treatment. The RCT that was the basis of FDA clearance of deep TMS for treatment of OCD compared deep TMS to sham in 99 patients for 6 weeks, with an additional 4 weeks of follow-up as a secondary outcome. Using a modified intention-to-treat (ITT) analysis (n=94), there was a larger mean decrease from baseline (improvement) on the Yale-Brown Obsessive Compulsive Scale (YBOCS) score (the primary efficacy outcome) in the active treatment group (-6.0 points) than the sham group (-2.8 points), translating to a moderate effect size of 0.69. At 6 weeks, the response rate was 38.1% in the active treatment group compared to 11.1% in the sham group (p=.003), as measured by a 30% or greater increase in the YBOCS. The difference in the primary outcome measure between active and sham groups was not statistically significant in the ITT analysis. There was a benefit for TMS on clinician-reported measures of improvement, but no significant difference between groups on patient-reported disability and impairment. Additional trials with sufficient sample size and follow-up duration are needed to confirm these results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric or neurological disorders other than depression, migraine, or OCD (e.g., bipolar disorder, generalized anxiety disorder, panic disorder, post-traumatic stress disorder, schizophrenia, substance use disorder and craving, amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, Parkinson disease, stroke recovery) who receive TMS, the evidence includes numerous small RCTs and meta-analyses of these randomized trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The trials included in the meta-analyses are typically small and of low methodologic quality. In addition, stimulation parameters have not been established, and trial results are heterogeneous. There are no large, high-quality trials for any of these conditions demonstrating

efficacy or the durability of any treatment effects. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The American Psychiatric Association (2018) published consensus recommendations on repetitive transcranial magnetic stimulation (rTMS) for the treatment of depression. The guidelines state, "Multiple randomized controlled trials and published literature have supported the safety and efficacy of rTMS antidepressant therapy." The recommendations include information on the following variables: clinical environment, operator requirements, documentation, coils, cortical targets, coil positioning methods, determination of motor threshold, number of treatment sessions for acute treatment, and allowable psychotropic medications during TMS treatment. The recommendations do not address use of one type of rTMS over another.

The American Psychiatric Association's (2007, reaffirmed in 2012) guidelines on the treatment of patients with obsessive-compulsive disorder have indicated that "findings of the 4 published trials of rTMS are inconsistent, perhaps because the studies differed in design, stimulation sites, duration, and stimulation parameters. The available results and the technique's non-invasiveness and good tolerability should encourage future research, but the need for daily treatment may limit the use of TMS in practice."

The Clinical TMS Society (2017) published consensus recommendations on TMS therapy for major depressive disorder. These recommendations concluded that clinical benefit was found within 6 weeks of daily treatment sessions. Continued treatment beyond 6 weeks in specific circumstances was also noted to have a clinical benefit.

The National Institute for Health and Care Excellence (2015) provided revised guidance, stating that evidence on the short-term efficacy of rTMS for depression is adequate, although the clinical response is variable and some patients may not benefit.

In 2014, the NICE provided guidance on the use of rTMS for treating and preventing migraine. The guidance stated that evidence on the efficacy of TMS for the treatment of migraine was limited in quantity and for the prevention of migraine was limited in both quality and quantity. Evidence on its safety in the short- and medium-term was adequate, but there was uncertainty about the safety of long-term or frequent use of TMS.

In 2020, the NICE stated that rTMS has not demonstrated any major safety concerns for management of obsessive-compulsive disorder or auditory hallucinations, but evidence for both uses is lacking; therefore, NICE recommends that rTMS be used in patients with these conditions only in the context of research.

## Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 90867, 90868, 90869, 0858T, 0889T, 0890T, 0891T, 0892T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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Specialty Matched Consultant Advisory Panel – 6/2020

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Specialty Matched Consultant Advisory Panel – 6/2022

Medical Director Review 6/2022

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Specialty Matched Consultant Advisory Panel – 6/2023

Medical Director Review 6/2023

Specialty Matched Consultant Advisory Panel – 6/2024

Medical Director Review 6/2024

## Policy Implementation/Update Information

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|---|---|
| 10/15/19 | New policy developed. TMS considered medically necessary as a treatment of major depressive disorder when criteria are met. Medical Director review 10/2019. (hb) |
| 3/10/20 | Description section updated. Clarified When covered statement to include all types of repetitive TMS. When covered section #4 added to require protocol and device be FDA approved. Note listing forms of rTMS added to Policy Guidelines for clarity. References added. (eel) |
| 3/24/20 | Regulatory section updated with FDA unit limits. Policy Guidelines updated with support of unit limits. Note added limiting units in When covered section. References added. **Policy noticed 3/24/20 for effective date 5/26/20.** (eel) |
| 9/08/20 | Clarification added to define the terms extension of initial therapy and maintenance to Policy Guidelines section. References added. Specialty Matched Consultant Advisory Panel review 6/17/2020. Medical Director review. No change to policy statement. (bb) |
| 1/26/21 | When covered section updated to clarify age requirement as "18 years or older" based on current FDA approval and criteria added for repeat rTMS. Medical Director review. References added. (bb) |
| 7/13/21 | References added. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review. No change to policy statement. (bb) |
| 7/12/22 | Related policies added. References added. Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. No change to policy statement. (tt) |
| 6/30/23 | Description updated with FDA approved devices. Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. No change to policy statement. (tt) |
| 12/29/23 | Added CPT code 0858T to Billing/Coding section, effective 1/1/2024. (tt) |
| 7/17/24 | Description, FDA approved devices, and Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review. No change to policy statement. Updated Billing/Coding section to add 0889T, 0890T, 0891T, 0892T, effective 7/1/2024. (tt) |