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Medical Policy

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

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Policy Number: 297

BCBSA Reference Number: 2.01.50 (For Plan internal use only)

NCD/LCD: Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (L33398)

Related Policies

- Outpatient Psychotherapy, #423
- Vagus Nerve Stimulation, #474
- Treatment of Tinnitus, #267
- Deep Brain Stimulation, #473

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity,

Repetitive transcranial magnetic stimulation (rTMS) or deep transcranial magnetic stimulation (dTMS) of the brain using an FDA-cleared device and modality may be considered <u>MEDICALLY NECESSARY</u> as a treatment of major depressive disorder when **all** of the following conditions (1-3) 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, c, or d):
 - 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. History of response to rTMS in a previous depressive episode (at least 3 months since the prior episode); or
 - d. 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.

Repetitive transcranial magnetic stimulation (rTMS) or deep transcranial magnetic stimulation (dTMS) for major depressive disorder that does not meet the criteria listed above is considered **INVESTIGATIONAL**.

Continued treatment with repetitive transcranial magnetic stimulation (rTMS) or deep transcranial magnetic stimulation (dTMS) or of the brain as maintenance therapy is considered **INVESTIGATIONAL**.

Repetitive transcranial magnetic stimulation (rTMS) or deep transcranial magnetic stimulation (dTMS) of the brain is considered INVESTIGATIONAL as a treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

Repetitive transcranial magnetic stimulation (rTMS) or deep transcranial magnetic stimulation (dTMS) should be performed using a U.S. Food and Drug Administration cleared device in appropriately selected patients, by physicians who are adequately trained and experienced in the specific techniques used. A treatment course should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

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.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (L33398)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed **inpatient**.

Outpatient

For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care	Prior authorization is required .
(HMO and POS)	Providers must submit the following form: Repetitive Transcranial
	Magnetic Stimulation (rTMS) Request Form
Commercial PPO and Indemnity	Prior authorization is required .

Medicare HMO Blue SM	Prior authorization is required.
Medicare PPO Blue SM	Prior authorization is required .

Requesting Prior Authorization Using Authorization Manager

Providers will need to use <u>Authorization Manager</u> to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the service request is processed accurately and guickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, not the billing group.

Authorization Manager Resources

Refer to our <u>Authorization Manager</u> page for tips, guides, and video demonstrations.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day (Report 0890T once on the first day of the course of treatment) (Do not report 0890T in conjunction with 77022)
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

Description

Transcranial Magnetic Stimulation

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.

Summary

Transcranial magnetic stimulation (TMS) is a noninvasive method of delivering electrical stimulation to the brain. The technique involves the placement of a small coil over the scalp and passing a rapidly alternating current through the coil wire. The electrical current produces a magnetic field that passes unimpeded through the scalp and bone and stimulates neuronal function. Repetitive TMS is being evaluated for the treatment of treatment-resistant depression (TRD) and other psychiatric and neurologic disorders. A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation. In conventional TMS, high frequency stimulation is delivered over the left dorsolateral prefrontal cortex (DLPFC) or low frequency stimulation over the right DLPFC. In bilateral TMS, both procedures are performed in the same session. Deep TMS employs an H-coil helmet designed 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 TMS.

For individuals who have treatment-resistant depression (TRD) who receive transcranial magnetic stimulation (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 (n=8 trials) and a sham-controlled RCT of 201 patients conducted for submission to the Food and Drug Administration (FDA) for clearance in 2013. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review found that repetitive TMS (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 (N=483 patients, range 18 to 65 patients) conducted in 2016 found a benefit of TMS on patientreported 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 patientreported 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 (eg, bipolar disorder, generalized anxiety disorder, panic disorder, posttraumatic 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.

Policy History

Date	Action
12/2024	Annual policy review. References updated. Policy statements unchanged.
7/2024	Policy clarified. Prior authorization is required on codes 90867 90868 90869 for
	commercial PPO products. Clarified coding information. Effective 7/1/2024.
12/2023	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
9/2023	Policy clarified to include prior authorization requests using Authorization Manager.
12/2022	Annual policy review. Policy statements unchanged.
12/2021	Annual policy review. Policy clarified to specify using an FDA-cleared device and
	modality. Policy statements otherwise unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for
	local coverage determination and national coverage determination reference.
12/2020	Annual policy review. Description, summary and references updated. Policy statements unchanged.
8/2020	Local Coverage Determination (LCD): Transcranial Magnetic Stimulation (L33398)
	added.
1/2020	Prior authorization requirement for Medicare HMO and PPO Blue clarified. Effective
	1/1/2020.
11/2019	Annual policy review. Description, summary and references updated. Policy
	statements unchanged.
3/22/2019	Prior authorization requirement for Medicare HMO Blue clarified. Effective 1/1/2019.
11/2018	Annual policy review. Description, summary and references updated. Policy statements unchanged.
8/2018	Annual policy review. Intent of policy statements unchanged. Prior authorization
	information clarified. Title changed. Effective 8/1/2018.
5/2015	New medical necessary indications described (coverage for deep rTMS added).
	Effective 5/1/2015.
12/2014	New investigational indications described (non-coverage for deep rTMS added).
	Effective 12/1/2014.
9/2014	Updated Medicare LCD. Effective 8/15/2014.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
7/2013	New medically necessary indications described for Commercial. Effective 7/1/2013.
3/2013	New medical policy, reflecting ongoing non-coverage of rTMS for commercial products,
	and new coverage criteria for Medicare Advantage products. Effective 3/17/2013.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

References

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