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

File Name: Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders File Code: 2.01.VT50 Origination: 07/2015 Last Review: 07/2023 Next Review: 11/2023 Effective Date: 11/01/2023

Description/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 (rTMS) 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.

The literature on TMS for individuals with treatment-resistant depression (TRD) includes a large number of sham-controlled randomized controlled trials (RCTs) and meta-analyses of these trials. 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 medically necessary 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 obsessivecompulsive disorder (OCD) or migraines who receive TMS, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome. There are also no large, high-quality trials demonstrating efficacy or the durability of TMS treatment effects 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 is insufficient to determine that the technology results in an improvement in the net health outcome. TMS is therefore considered investigational for these other psychiatric and neurologic conditions.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions. <u>Attachment I- CPT ©Code List & Instructions</u>

When a service may be considered medically necessary

Transcranial magnetic stimulation (TMS) of the brain, which can include but is not limited to conventional TMS, deep TMS, and theta burst stimulation, may be considered **medically necessary** as a treatment of major depressive disorder when all of the following conditions (1-5) have been met:

1. Confirmed diagnosis of severe major depressive disorder (single or recurrent episode) documented by standardized rating scales that reliably measure depressive symptoms;

AND

- **2.** Any one of the following (a, b, c, or d):
 - a. Individual has tried and had an inadequate response to 2 antidepressant agents from 2 different antidepressant classes (i.e., selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, tricyclic antidepressants,

bupropion, or mirtazapine). An adequate trial of an antidepressant is defined by BOTH of the following:

- 1. The trial length was at least 6 weeks at generally accepted doses or of sufficient duration as determined by the treating physician at the generally accepted doses; AND
- 2. Individual was \geq 80% adherent to the agent during the trial.
- b. Inability to tolerate a therapeutic dose of medications due to distinct side effects; **OR**
- c. History of treatment response (e.g., greater than 50% improvement in the individual's depressive symptoms as evidenced by a standard rating scale that reliably measures depressive symptoms) to TMS in a previous depressive episode (at least 3 months since the prior episode); **OR**
- d. Is a candidate for electroconvulsive therapy (ECT) and ECT would not be clinically superior to TMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening situation TMS should NOT be utilized);

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. TMS treatment is administered by a U.S. Food and Drug Administration (FDA) cleared device for the treatment of major depressive disorder (MDD) according to one of the following specified stimulation parameters and protocols:
 - a. Standard treatment course: 30 sessions, each lasting 30-60 minutes, over a 6-week period followed by a 3-week taper of 3 TMS treatments in 1 week, 2 TMS treatments the next week, and 1 TMS treatment in the last week (for a total of 36 standard sessions), OR
 - b. Accelerated treatment course (SAINT protocol): 10 sessions per day, each lasting about 10 minutes, for a total of 5 consecutive days (for a total of 50 accelerated sessions);

AND

- 5. None of the following conditions or contraindications to TMS are present:
 - Seizure disorder or any history of seizure with increased risk of future seizure

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

NOTE: An extension of a full course of TMS may be considered **medically necessary** when:

- The individual has not experienced improvement; **OR**
- The individual has had a partial response, but symptoms are still moderate or severe as demonstrated by documentation of the individual's symptoms and their severity or by a standardized rating scale; **OR**
- The individual had minimal to no response until after the first 15 treatments ("slow/late responder'); **OR**
- The individual had a positive response but then symptoms worsened during a taper or within a few days of completing treatment; **OR**
- The individual has had a good response, symptoms have improved to mild, but the goal is to reach remission or as close as possible to remission; **AND**
- The extension of the intensive course or phase consists of one treatment daily 4-5 days per week for a maximum of 10 total treatments if symptoms are mild, 15 total treatments if symptoms are moderate, or 20 total treatments if symptoms are severe; AND
- If symptoms are mild or moderate, one session may include motor threshold re-determination; if symptoms are severe, 1-2 sessions may include motor threshold re-determination;

When a service is not medically necessary

An extension of a full course of TMS that does not meet the criteria listed above is considered **not medically necessary.**

When a service is considered investigational

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

Maintenance TMS (also referred to as relapse prevention), which is the continuation of TMS after a full intensive course at reduced frequency in order to maintain improvement, is

considered investigational.

TMS 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.

Policy Guidelines

TMS must be administered by using a U.S. Food and Drug Administration (FDA)–cleared device in appropriately selected individuals over age 18 years by a board-certified psychiatrist (MD/DO) trained in TMS therapy, or by a trained technician working under the supervision of a board-certified psychiatrist trained in TMS therapy. While a trained technician working under the supervision of a board-certified psychiatrist trained in TMS therapy may administer the treatment, a board-certified psychiatrist trained in TMS therapy must be present in the area and immediately available. A variety of TMS modalities have been developed and approved for use by the FDA for the treatment of major depressive disorder (MDD); these modalities 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. Theta burst stimulation is administered at lower intensities and at shorter intervals than conventional TMS. Deep TMS employs an H-coil helmet designed to encompass a broader surface area and stimulate deeper brain structures than conventional TMS.

The following should be present for the administration of TMS:

- a. An attendant trained in basic cardiac life support and the management of complications such as seizures, as well as the use of the equipment must be present at all times; **AND**
- b. Adequate resuscitation equipment including, for example, suction and oxygen; AND
- c. The facility must maintain awareness of response times of emergency services (either fire/ambulance or "code team"), which should be available within five minutes. These relationships are reviewed at least annually and include mock drills.

Reference Resources

- 1. Blue Cross and Blue Shield Association Medical Policy Manual, Policy Number: 2.01.50. Last Reviewed November 2022.
- Anthem Transcranial Magnetic Stimulation Policy. Retrieved from: https://providers.anthem.com/docs/gpp/VA_CCC_BH_TranscranialMagneticStimulat ionRequest.pdf?v=202106231625.
- Department of Vermont Health Access—Transcranial Magnetic Stimulation Clinical Practice Guidelines. Retrieved from: https://humanservices.vermont.gov/sites/ahsnew/files/documents/MedicaidPolicy/GCRP roposedPolicies/20-078-TMS-Guidance.pdf

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

07/2015 New policy. Adopted BCBSA policy#2.01.50. Approved by medical policy committee on 3/30/15. Effective 1/1/16. Next review 2017

01/2017	Removed ICD 9 codes, Updated ICD Codes added F32.89 deleted F32.8, Updated references, updated formatting to align to BCBSA MPRM # 2.01.50
11/2018	No changes to policy. Removed ICD-10-CM table.
10/2020	Reviewed by medical director and HPT. No substantive changes were made to policy, including no textual or coding changes. Removed references and left the Blue Cross Blue Shield Association TMS policy as sole reference.
12/2021	Reviewed Policy. Added language related to repetitive transcranial magnetic stimulation medically necessity criteria. Updated references.
11/2022	Reviewed policy. Updated language, including addition of theta burst stimulation to TMS modalities. Updated medical necessity criteria to align with Association policy re the required number and extent of prior medication trials. Small grammatical changes. References updated.
07/2023	Reviewed policy. Received input from network provider. Changes to policy statement around protocol and session medical necessity as well as provider qualifications to administer treatment.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Tom Weigel, MD, MBA Vice President and Chief Medical Officer

Tammaji P. Kulkarni, MD Senior Medical Director

Code Type	Number	Description	Policy Instructions			
The following codes will be considered as medically necessary when applicable criteria have been met.						
CPT®	90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management	Prior Approval Required			
CPT®	90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session	Prior Approval Required			

<u>Attachment I</u> CPT® Code List & Instructions

CPT®	90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management	Prior Approval Required
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