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

Description of Procedure or Service

Transcranial magnetic stimulation (TMS), was introduced in 1985 as a method of noninvasive stimulation of the brain. It 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. TMS 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. The stimulation site for treatment of depression is usually 5 cm anterior to the motor stimulation site.

In contrast to electroconvulsive therapy, TMS does not require general anesthesia and does not generally induce a convulsion. 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 activity of the left dorsolateral prefrontal cortex (DLPFC) in depressed patients, and early studies suggested that high-frequency (eg, 5-10 Hz) TMS of the left DLPFC had antidepressant effects. Low-frequency (1-2 Hz) stimulation of the right DLPFC has also been investigated. The rationale for low-frequency TMS is inhibition of right frontal cortical activity to correct the interhemispheric imbalance. A combination approach (bilateral stimulation), or deep stimulation with a specialized H1 coil attachment may also be used.

Repetitive TMS (rTMS) is also being tested as a treatment for a variety of other disorders including alcohol dependence, Alzheimer disease, neuropathic pain, obsessive-compulsive disorder, postpartum depression, Parkinson disease, stroke, posttraumatic stress disorder, panic disorder, epilepsy, dysphagia, Tourette syndrome, schizophrenia, migraine, spinal cord injury, fibromyalgia, and tinnitus. In addition to the potential for altering interhemispheric imbalance, it has been proposed that high-frequency rTMS may facilitate neuroplasticity.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Indication</th>
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<tbody>
<tr>
<td>Neurostar</td>
<td>Neuronetics</td>
<td>Major Depressive Disorder</td>
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<tr>
<td>Brainsway Deep TMS System</td>
<td>Brainsway</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Rapid Therapy System</td>
<td>Magstim</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Magvita</td>
<td>Tonica Elektronik</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Neurosoft</td>
<td>TeleEMG</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Horizon</td>
<td>Magstim</td>
<td>Major Depressive Disorder</td>
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<tr>
<td>Nexstim</td>
<td>Nexstim</td>
<td>Major Depressive Disorder</td>
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<tr>
<td>Apollo</td>
<td>Mag &amp; More</td>
<td>Major Depressive Disorder</td>
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<tr>
<td>Intermittent Theta Burst Stimulation (iTBS)</td>
<td>Magstim</td>
<td>Major Depressive Disorder</td>
</tr>
<tr>
<td>Theta Burst Stimulation (TBS)</td>
<td>Magventure</td>
<td>Major Depressive Disorder</td>
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</table>

***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.

**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 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, c, or d):
   a. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; or
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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; and

4. Device is FDA approved and utilized in accordance with the FDA labeled indication of major depressive disorder.

For initial 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:

- Seizure Disorder or any history of seizure with increased risk of future seizure; or
- Presence of acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
- 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
- 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.
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Policy Guidelines

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

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

For individuals who have TRD who receive rTMS, the evidence includes a large number of sham-controlled randomized trials and meta-analyses of these trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. The meta-analyses found a clinical benefit associated with rTMS for TRD with improved response rates and rates of remission compared with sham. The most recent meta-analyses have concluded that the effect of rTMS, on average depression scores, is smaller than the effect of ECT on TRD and that the mean improvement in depression scores with rTMS 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 rTMS is in accelerating or enhancing the response to antidepressant medications, and there is some evidence that rTMS, when given in conjunction with the initiation of pharmacologic therapy, improves the response rate compared with pharmacologic therapy alone. The effect of rTMS 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 rTMS decreases with longer follow-up, though some studies have reported 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 rTMS appear to be minimal. While the most recent meta-analyses have reported that the effect of rTMS is smaller than the effect of ECT on TRD, because rTMS does not require general anesthesia or induce seizures, some individuals may decline ECT so the balance of incremental benefits and harms associated with rTMS may be a 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, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence for theta burst stimulation includes a large randomized trial showing noninferiority with another method of rTMS; no significant differences were noted in the number of adverse events. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have psychiatric or neurologic disorders other than depression (e.g., amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, migraine headache, obsessive-compulsive disorder, panic disorder, Parkinson disease, posttraumatic stress disorder, schizophrenia, stroke, substance abuse and craving) who receive rTMS, 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 the effects of the technology on health outcomes.

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
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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 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.

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

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

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments. 2009;Volume 24:Tab 5.

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. TEC Assessments. 2011;Volume 26:Tab 3.


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**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>10/15/19</td>
<td>New policy developed. TMS considered medically necessary as a treatment of major depressive disorder when criteria are met. Medical Director review 10/2019. (hb)</td>
</tr>
<tr>
<td>3/10/20</td>
<td>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)</td>
</tr>
<tr>
<td>3/24/20</td>
<td>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. <strong>Policy noticed 3/24/20 for effective date 5/26/20.</strong> (eel)</td>
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.