BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.50 Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

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Related Policies:

2.01.90 - Navigated Transcranial Magnetic Stimulation

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

Description

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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.

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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 (TMS) is also being tested as a treatment for a variety of other psychiatric and neurologic disorders.

OBJECTIVE

The objective of this evidence review is to evaluate whether the use of repetitive transcranial magnetic stimulation of the brain improves the net health outcome for individuals with various psychiatric or neurologic conditions.

POLICY STATEMENT

Transcranial magnetic stimulation (TMS) of the brain using an FDA-cleared device and modality, which can include but is not limited to, conventional TMS, deep TMS, and theta burst stimulation (see Policy Guidelines) may be considered **medically necessary** as a treatment of major depressive disorder when all of the following conditions (1 to 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 (1, 2, 3, or 4):
    1. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; or
    2. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; or
    3. History of response to TMS in a previous depressive episode (at least 3 months since the prior episode); or
    4. Is a candidate for electroconvulsive therapy; further, electroconvulsive therapy would not be clinically superior to TMS (eg, in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition TMS 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.

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

Continued treatment with TMS of the brain as maintenance therapy is considered **investigational**.

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.

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POLICY GUIDELINES

Repetitive Transcranial magnetic stimulation (TMS) should be performed using a U.S. Food and Drug Administration cleared device in appropriately selected patients over age 18 years, by physicians who are adequately trained and experienced in the specific techniques used.

A treatment course of conventional TMS 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.

Theta burst stimulation may be administered using an accelerated protocol. One example of an accelerated theta burst protocol is the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol, consisting of 10 daily sessions over 5 consecutive days.

Contraindications to repetitive TMS include:

1. Seizure disorder or any history of seizure with increased risk of future seizure; or
2. Presence of acute or chronic psychotic symptoms or disorders (eg, schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; or
3. 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
4. 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, pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

The following should be present for the administration of repetitive TMS:

1. 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 arial; and
2. Adequate resuscitation equipment including, eg, suction and oxygen; and
3. The facility must maintain awareness of response times of emergency services (either fire/ambulance or "code team"), which should be available within 5 minutes. These relationships are reviewed on at least a 1-year basis and include mock drills.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Devices for transcranial stimulation have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for diagnostic uses (FDA Product Code: GWF). A number of devices subsequently received 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. Some of these devices use deep TMS or theta burst protocols. For example, the Brainsway Deep TMS system was FDA cleared for treatment resistant depression in 2013 based on substantial equivalence to the Neurostar TMS Therapy System, and the Horizon (Magstim) and MagVita (Tonica Elektronik) have FDA clearance for their theta burst protocols.

Indications were expanded to include treating pain associated with certain migraine headaches in 2013, and obsessive-compulsive disorder in 2018.

In 2014, eNeura Therapeutics received 510(k) marketing clearance for the SpringTMS for the treatment of migraine headaches. The device differs from the predicate Cerena™ TMS device with the addition of an LCD screen, a use authorization feature, a lithium battery pack, and a smaller size. The stimulation parameters are unchanged. The sTMS Mini (eNeura Therapeutics) received marketing clearance by the FDA in 2016. FDA product code: OKP.

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In August 2018, the Deep TMS System (Brainsway) was granted a de novo 510(k) classification by the FDA as an adjunct for the treatment of adult patients with obsessive-compulsive disorder. The new classification applies to this device and substantially equivalent devices of this generic type.

The NeoPulse, now known as NeuroStar TMS, was granted a de novo 510(k) classification by the FDA in 2008. The de novo 510(k) review process allows novel products with moderate or low-risk profiles and without predicates, which would ordinarily require premarket approval as a class III device, to be down-classified in an expedited manner and brought to market with a special control as a class II device.

In 2014, the Cerena™ TMS device (eNeura Therapeutics) was granted a de novo 510(k) classification by the FDA for the acute treatment of pain associated with migraine headache with aura. Warnings, precautions, and contraindications include the following:

- The device is only intended for patients experiencing the onset of pain associated with a migraine headache with aura.
- The device should not be used:
    - on headaches due to underlying pathology or trauma.
    - for medication overuse headaches.
- The device has not been demonstrated as safe and/or effective:
    - when treating cluster headache or a chronic migraine headache.
    - when treating during the aura phase.
    - in relieving the associated symptoms of a migraine (photophobia, phonophobia, and nausea).
    - in pregnant women, children under the age of 18, and adults over the age of 65.

Table 1 lists some devices that are FDA cleared for major depressive disorder (Product Code: OBP), migraine headache pain (Product Code: OKP), and obsessive-compulsive disorder (Product Code: QCI).

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Table 1. Repetitive TMS Devices Cleared by FDA for Major Depression, Migraine, or Obsessive-Compulsive Disorder

Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
Neurostar	Neuronetics	Major Depressive Disorder	K083538	12/16/2008
Brainsway Deep TMS System	Brainsway	Major Depressive Disorder	K122288	01/07/2013
		Obsessive-Compulsive Disorder	K183303	03/08/2019
Springtms Total Migraine System	Eneura	Migraine headache with aura	K140094	05/21/2014
Rapid Therapy System	Magstim	Major Depressive Disorder	K143531	05/08/2015
Magvita	Tonica Elektronik	Major Depressive Disorder	K150641	07/31/2015
Mag Vita TMS Therapy System w/Theta Burst Stimulation	Tonica Elektronik	Major Depressive Disorder	K173620	8/14/2018
Neurosoft	TeleEMG	Major Depressive Disorder	K160309	12/22/2016
Horizon	Magstim	Major Depressive Disorder	K171051	09/13/2017
Horizon TMS Therapy System (Theta Burst Protocol)	Magstim	Major Depressive Disorder	K182853	03/15/2019
Nexstim	Nexstim	Major Depressive Disorder	K171902	11/10/2017
Apollo	Mag & More	Major Depressive Disorder	K180313	05/04/2018

FDA: U.S. Food and Drug Administration; TMS: transcranial magnetic stimulation.

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RATIONALE

Summary of Evidence

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 sham-controlled randomized controlled trial (RCT) of 201 patients conducted for submission to the U.S. Food and Drug Administration for clearance in 2013. Relevant outcomes are symptoms, functional outcomes, and quality of life. 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 18-65 patients) 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 22 RCTs. Three of 5 TMS protocols assessed were significantly more efficacious than sham TMS, and all treatment strategies were similar to sham TMS regarding tolerability. Deep TMS was not more effective than sham TMS, but there was direct evidence from only 1 RCT for this comparison. The overall quality of the evidence was rated very low for efficacy and low for tolerability, and the reviewers concluded that high quality RCTs with low selection and performance bias are needed to further verify the efficacy of specific TMS strategies for OCD 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 (eg, amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, panic disorder, Parkinson disease, posttraumatic stress disorder, schizophrenia, stroke, substance use disorder, and craving) 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.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Child and Adolescent Psychiatry

In 2013, the American Academy of Child and Adolescent Psychiatry published practice parameters on the assessment and treatment of children and adolescents with tic disorders.[49,] The Academy did not recommend rTMS, citing the limited evidence on the safety, ethics, and long-term impact on development.

American Psychiatric Association

The American Psychiatric Association (2018) published consensus recommendations on rTMS for the treatment of depression.[50,] 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 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."

National Institute for Health and Care Excellence

In 2015, the National Institute for Health and Care Excellence (NICE) 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.[51,]

In 2014, the NICE provided guidance on the use of rTMS for treating and preventing migraine.[52,] 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
March 2013	Replace policy	Policy reviewed and rationale updated for non-FDA approved indications. No change in policy statement. New FDA approved device added.
March 2015	Replace policy	Policy updated with literature review through October 30, 2014; references 15, 17, 25, 27, 36, 41, 48, 52, 53, and 55 added and some references removed; policy statements are unchanged.
June 2016	Replace policy	Policy updated with literature review through November 9, 2015; references 17, 36, 43, 46, and 48 added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through August 23, 2018; references 9, 10, 19, 21, 24, 29, 31, 35 and 37 added. Policy statements unchanged except "not medically necessary" revised to "investigational" to align with FDA 510(k) status.
December 2019	Replace policy	Policy updated with literature review through August 26, 2019; references added. Policy statements unchanged.
October 2020	Replace policy	Policy updated with literature review through September 12, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through September 3, 2021; references added. Medically necessary policy statement on transcranial magnetic stimulation (TMS) for treatment resistant depression revised to specify "using an FDA-cleared device and modality, which can include but is not limited to, conventional TMS, deep TMS, and theta burst stimulation." Information on different modalities including theta burst stimulation added to the Policy Guidelines. Policy statements otherwise unchanged.

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