MEDICAL POLICY

SUBJECT: TRANSCRANIAL MAGNETIC STIMULATION **POLICY NUMBER: 3.01.09** **CATEGORY: Technology Assessment**	**EFFECTIVE DATE: 08/20/09** **REVISED DATE: 07/15/10, 08/18/11, 11/15/12, 12/19/13, 12/18/14, 10/15/15, 12/15/16, 12/21/17** **PAGE: 1 OF: 14**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Based upon our review and assessment of peer-reviewed literature, transcranial magnetic stimulation has been medically proven to be effective and is be considered **medically appropriate** as a treatment of major depressive disorder when ALL (A, B, and C) of the following conditions have been met:

A. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms with the failure of at least one prior antidepressant medication in the current treatment episode; AND

B. Any one of the following (1, 2, or 3,):

1. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials (*please see guidelines section, roman numeral II and III*); OR
2. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; OR
3. Is a candidate for electroconvulsive therapy (ECT) and ECT would not be clinically superior to rTMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized); AND

C. 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.

II. Based upon our review and assessment of peer-reviewed literature, a request for transcranial magnetic stimulation as a treatment for major depressive disorder that does not meet all the above listed criteria is considered **not medically necessary.**

III. Based upon our review and assessment of peer-reviewed literature continued treatment with TMS as maintenance therapy has not been medically proven to be effective and is considered **investigational**.

IV. Based upon our review and assessment of peer-reviewed literature, transcranial magnetic stimulation has not been medically proven to be effective and is considered **investigational** as a treatment of all other psychiatric/neurologic disorders, including but not limited to, bipolar disorder, borderline personality disorder, schizophrenia, obsessive compulsive disorder, or migraine headaches.

V. Based upon our review and assessment of peer-reviewed literature, retreatment with transcranial magnetic stimulation has been medically proven to be effective and is be considered **medically appropriate** for patients who met the guidelines for initial treatment AND have subsequently developed relapse of depressive symptoms . The patient must have responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms.

Refer to Corporate Medical Policy #8.01.07 regarding Tinnitus Treatment.

POLICY GUIDELINES:

I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

II. An adequate trial of medication is based on a combination of duration, dosage, tolerance and efficacy of medication. Duration is usually 4-6 weeks (as evidenced by the STAR*D trial); dosing is dependent on the medication as some medications have a single strength only while others have a minimally effective- maximum effective range. Patients may have more side effect issues or poor tolerance when medications are given at the higher dose ranges. The severity of initial depression and /or the amount of comorbid illness can slow the time to improvement utilizing medication. Providers are required to document medication trials, including the duration, dosing, and side effects when submitting requests for transcranial magnetic stimulation.

III. The medication regimen can also include use of evidenced-based augmenters or adjunct medications that are not antidepressants themselves; or use of combination therapy when 2 antidepressants are used to together. Examples include Fluoxetine with Bupropion added as combination therapy-augmentation or citalopram and buspirone as and adjunctive augmentation.

IV. Transcranial magnetic stimulation should be performed 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 transcranial magnetic stimulation (TMS) treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

V. Standardized Rating Scale reliable in rating depressive symptoms include validated depression monitoring scales such as: Geriatric Depression Scale (GDS); Personal Health Questionnaire Depression Scale (PHQ-9); Beck Depression Scale (BDI) Hamilton Rating Scale for Depression (HAM-D) Montgomery Asberg Depression Rating Scale (MADRS); Quick Inventory of Depressive symptomatology (QIDS); or Inventory for Depressive symptomatology Systems Review (IDS-SR).

VI. There are many complementary/ancillary therapies that are not evidence based, or have only low quality evidence that they help in the treatment of depression. There is no evidence that vitamins, supplements, hypnosis, genetic testing, massage are required to make a course of TMS more effective. If there is a particular activity that a provider is adding to TMS, please refer to the member contract or specific medical policy to determine coverage requirements.

VII. Motor threshold is initially assessed during the first treatment session. Measurement of the motor threshold varies from individual to individual and determines the amount of energy required to stimulate brain cells. This allows for individualization of the intensity of stimulation. It is not medically necessary to check motor threshold at every treatment but motor threshold may be reassessed if there is concern that it may have changed, for example, because of a change in medication. Requests for multiple motor thresholds during the course of rTMS treatment will require documentation to prove medical necessity.

DESCRIPTION:

The majority of individuals treated for depression respond to standard treatments for depression (e.g., psychotherapy, pharmacotherapy, or electroconvulsive therapy [ECT]). One of the alternative treatments being investigated for those patients who do not benefit or cannot tolerate these standard therapies is transcranial magnetic stimulation.

Transcranial magnetic stimulation was initially used to investigate nerve conduction; for example, transcranial magnetic stimulation over the motor cortex will produce a contralateral muscular-evoked potential. The technique involves placement of a small coil over the scalp; a rapidly alternating current is passed through the coil wire, producing a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex. In the course of its use, mood effects have been observed, and interest in developing TMS as a treatment for depression followed. Imaging studies had showed a decrease in activity of the left dorsolateral prefrontal cortex

(DLPFC) in depressed patients, and early studies suggested that high frequency (e.g., 5–10 Hz) TMS of the left DLPFC had antidepressant effects. Investigation into the use of transcranial magnetic stimulation as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation, known as rTMS. Over time, improvements in coil design have allowed more focal stimulation, and the prefrontal cortex has been the region of interest in many recent studies in which rTMS was used in the treatment of depression. In contrast to electroconvulsive therapy, transcranial magnetic stimulation can be performed in an office setting as it does not require anesthesia and does not induce a convulsion. TMS is also being tested as a treatment for other disorders including, but not limited to, schizophrenia, obsessive-compulsive disorder, bulimia, Parkinson's disease, Tourette's syndrome, migraines, chronic pain syndromes, and fibromyalgia.

RATIONALE:

In October 2008, the NeuroStar TMS device (Neuronetics, Inc.) received FDA marketing clearance utilizing the FDA's "de novo" device clearance classification. TMS therapy is indicated for patients with treatment-resistant depression who have failed one 6-week course of antidepressant medication. The Brainsway Company received FDA clearance for its Deep TMS device in January 2013. It is indicated for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. On July 31, 2015, the FDA cleared MagVita TMS Therapy System (MegVenture) for the treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The Rapid Therapy System (Magstim Company, LTD) also received FDA approval in 2015 and is indicated for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Neurosoft TMS (TeleEMG, LLC) received FDA 510(k) clearance in 2016 as a predicate device for the treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

On December 13, 2013, a TMS device, The Cerena Transcranial Magnetic Stimulator (TMS) (eNeura Therapeutics, Sunnyvale, CA) received FDA approval thru the de novo premarket review pathway to market the Cerena TMS device. This is the first device to relieve pain caused by migraine headaches that are preceded by an aura: a visual, sensory or motor disturbance immediately preceding the onset of a migraine attack. In 2014, eNeura Therapeutics received 510(k) marketing clearance for the SpringTMS® for the treatment of migraine headache. The device differs from the predicate Cerena™ TMS device with the addition of an LCD screen, a use authorization feature, lithium battery pack, and smaller size. The stimulation Parameters are unchanged. The sTMS Mini (eNeura Therapeutics) received marketing clearance by the FDA in 2016.

Lam and colleagues (2008) conducted a meta-analysis of 24 randomized controlled trials comparing active versus sham rTMS in patients with treatment-resistant depression, although there were varying definitions of treatment-resistant depression. This analysis calculated a number needed to treat of 6, with a clinical response in 25% of active rTMS and 9% of sham rTMS patients. Remission was reported for 17% of active rTMS and 6% of sham rTMS patients. The largest study (23 study sites) included in the meta-analysis was a double-blind multicenter trial with 325 treatment-resistant depression patients randomized to daily sessions of high frequency active or sham rTMS (Monday to Friday for 6 weeks) of the left dorsolateral prefrontal cortex. Treatment-resistant depression was defined as failure of at least one adequate course of antidepressant treatment. Patients had failed an average of 1.6 treatments in the current episode, with about half of the study population failing to benefit from at least 2 treatments. Loss to follow-up was similar in the 2 groups, with 301 (92.6%) patients completing at least one post-baseline assessment and an additional 8% of patients from both groups dropping out before the 4-week assessment. Intent-to-treat analysis showed a trend favoring the active rTMS group in the primary outcome measure (2 points on the Montgomery-Asberg Depression Rating Scale; $p = 0.057$) and a modest (2-point) but significant improvement over sham treatment on the HAM-D. The authors reported that after 6 weeks of treatment the subjects in the active rTMS group were more likely to have achieved remission than the sham controls (14% vs. 5%), although this finding is limited by loss to follow-up.

Another randomized sham-controlled double-blind trial was conducted in 68 patients who had failed at least 2 courses of antidepressants. (Avery, et al. 2006) Three patients in each group did not complete the 15 treatment sessions or were

excluded due to a change in medication during treatment, resulting in 91% follow-up. Independent raters found a clinical response in 31% (11 of 35) of the active rTMS patients and 6% (2 of 33) of the sham group. The average change in HAM-D was 7.8 for the active group and 3.7 for the control group. The BDI decreased by 11.3 points in the active rTMS group and 4.8 points in controls. Remission was observed in 7 patients (20%) in the active rTMS group and 1 patient (3%) in the control group. Regarding effectiveness of blinding; 15% of subjects in each group guessed that they were receiving active TMS after the first session. After the 15th session, 58% of the rTMS group and 43% of the sham group guessed that they had received active TMS; responders were more likely than non-responders (85% vs. 42%) to think that they had received the active treatment. The 11 responders were treated with antidepressant medication and followed up for 6 months. Of these, 1 was lost to follow-up, 5 (45%) relapsed, and 5 (45%) did not relapse.

Several studies have compared the outcomes of rTMS with those from electroconvulsive therapy. McLoughlin, et al. (2007) studied forty-six patients who had been referred for electroconvulsive therapy were randomized to either electroconvulsive therapy (average of 6.3 sessions) or a 15-day course (5 treatments per week) of rTMS of the left dorsolateral prefrontal cortex. Electroconvulsive therapy resulted in a 14-point improvement in the HAM-D and a 59% remission rate. rTMS was less effective than electroconvulsive therapy (5-point improvement in HAM-D and a 17% remission rate).

The evidence for repetitive transcranial magnetic stimulation (rTMS) in patients who have treatment resistant depression (TRD) includes numerous double-blind, randomized sham-controlled short-term trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. Results of these trials show small mean improvements across groups as a whole. The percentage of subjects who show a clinically significant response is reported at approximately 2 to 3 times that of sham controls, with approximately 15% to 25% of patients meeting the definition of clinical response. Based on the short-term benefit observed in randomized controlled trials and the lack of alternative treatments, aside from electroconvulsive therapy in patients with TRD, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Contraindications to rTMS include: 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) in the current depressive episode; 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 (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.

A 2015 meta-analysis (Kedzior, et al.) examined durability of the antidepressant effect of high-frequency rTMS of the left DLPFC in the absence of maintenance treatment. Included were double-blind, sham-controlled RCTs with a total of 495 patients. The range of follow-up was 1 to 16 weeks, but most studies only reported follow-up to 2 weeks. The overall effect size was small with a standardized mean difference (SMD; Cohen's *d*) of -.48, and the effect sizes were lower in RCTs with 8- to 16-week follow-up (*d* = -.42) than with 1- to 4-week follow-up (*d* = -0.54). The effect size was higher when antidepressant medication was initiated concurrently with rTMS (5 RCTs, *d* = -.56) than when patients were on a stable dose of medication (9 RCTs, *d* = -.43) or were unmedicated (2 RCTs, *d* = -.26).

In 2014, Dunner and colleagues reported 1-year follow-up with maintenance therapy from a large multicenter observational study (42 sites) of rTMS for patients with TRD. A total of 257 patients agreed to participate in the follow-up study of 307 who were initially treated with rTMS. Of these, 205 completed the 12-month follow-up, and 120 patients had met the Inventory of Depressive Symptoms-Self Report response or remission criteria at the end of treatment. Ninety-three of the 257 patients (36.2%) who enrolled in the follow-up study received additional rTMS (mean, 16.2 sessions). Seventy-five of the 120 patients (62.5%) who met response or remission criteria at the end of the initial treatment phase (including a 2 month taper phase) continued to meet response criteria through follow-up.

Fitzgerald, et al. reported a prospective open-label trial of clustered maintenance rTMS for patients with TRD. All patients had received a second successful course of rTMS following relapse and were then treated with monthly maintenance therapy consisting of 5 rTMS treatments over a 2.5-day period (Friday evening, Saturday, and Sunday). Of 35 patients, 25 (71%) relapsed at a mean of 10.2 months (range, 2- 48 months).

Overall, the outcome data related to maintenance therapy is insufficient to determine the overall benefit on health outcomes. Additional data are needed related to durability of effect and to maintenance therapy.

The largest area of TMS research outside of depressive disorders appears to be treatment of auditory hallucinations in schizophrenia resistant to pharmacotherapy. Fitzgerald et al. (2005) conducted a randomized double-blind trial of 33 patients with treatment-resistant auditory hallucinations. rTMS was applied for 10 consecutive days for 15 minutes at 1 Hz and 90% of the resting motor threshold. The investigators found that active treatment did not result in a greater therapeutic effect than sham on any measure except for the loudness of the hallucinations, with a reduction in the active versus the sham group. The authors concluded that the study did not support the effectiveness of rTMS using the stimulation parameters provided.

A meta-analysis (Aleman et al. 2007) was conducted to investigate the efficacy of rTMS treatment of hallucinations. A total of 15 studies were identified that reported empirical data regarding rTMS treatment of auditory hallucinations. Ten of the studies met the inclusion criteria with a total of 212 patients. The authors concluded that rTMS may prove to be a promising method for reducing the frequency and intensity of auditory hallucinations in treatment-resistant patients, but larger clinical trials with follow-up are needed to establish the clinical efficacy of this treatment.

Two small (n = 14 and 18) randomized sham-controlled trials found no evidence of efficacy for treatment of bulimia nervosa or obsessive compulsive disorder. (Walpoth, et al 2008, Sachdev, et al. 2007, respectively).

Evidence related to the efficacy of rTMS for other disorders such as ALS, Tourette's, fibromyalgia, Alzheimer's disease, stroke, Parkinson disease, tinnitus, headaches, or chronic pain is limited (e.g., Gou, et al. 2011, Kwon, et al. 2011, Short, et al. 2011, Benninger, et al. 2012, Yang, et al. 2013, Peng, et al. 2012, Ahmed, et al. 2011, O'Connell, et al. 2011, respectively). Studies are plagued by methodological limitations such as small samples sizes and limited follow-up. The role that TMS has in the treatment of these disorders has not been established.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	90867	Therapeutic repetitive transcranial magnetic stimulation treatment; initial, including cortical mapping, motor threshold determination, delivery and management
	90868	Therapeutic repetitive transcranial magnetic stimulation; subsequent delivery and management, per session
	90869	Therapeutic repetitive transcranial magnetic stimulation; subsequent motor threshold re-determination with delivery and management

HCPCS: No specific codes

ICD9:	296.23	Major depressive affective disorder, single episode severe degree, without psychotic behavior
	296.33	Major depressive affective disorder, recurrent episode severe degree, without psychotic

behavior

ICD10: F32.0-F32.9 Major depressive disorder, single episode (code range)

F33.0-F33.9 Major depressive disorder, recurrent (code range)

REFERENCES:

Agency for Healthcare Research and Quality (AHRQ). Comparative effectiveness review number 33. Nonpharmacologic interventions for treatment-resistant depression in adults. 2011 Sep. [http:www.effectivehealthcare.qhrq.gov/reports/final.cfm] accessed 11/14/17.

Ahmed MA, et al. Effects of low versus high frequencies of repetitive transcranial magnetic stimulation on cognitive function and cortical excitability in Alzheimer's dementia. J Neurol 2012 Jan;259(1):83-92.

*Aleman A, et al. Efficacy of slow repetitive transcranial magnetic stimulation in the treatment of resistant auditory hallucinations in schizophrenia: a meta-analysis. J Clin Psychiatry 2007 Mar;68(3):416-21.

Allan CL, et al. Transcranial magnetic stimulation in the management of mood disorders. Neuropsychobiology 2011;64(3):163-9.

American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder. 2010 Oct [http://psychiatryonline.org/guidelines.aspx] accessed 11/14/17.

*Avery DH, et al. A controlled study of repetitive transcranial magnetic stimulation in medication-resistant major depression. Biol Psychiatry 2006 Jan 15;59(2):187-94.

*Avery DH, et al. Transcranial magnetic stimulation reduces pain in patients with major depression: a sham-controlled study. J Nerv Ment Dis 2007 May;195(5):378-81.

*Avery DH, et al. Transcranial magnetic stimulation in the acute treatment of major depressive disorder: clinical response in an open-label extension trial. J Clin Psychiatry 2008 Mar;69(3):441-51.

Bakker N, et al. rTMS of the dorsomedial prefrontal cortex for major depression: safety, tolerability, effectiveness, and outcome predictors for 10 Hz versus intermittent theta-burst stimulation. Brain Stimul 2015 Mar-Apr;8(2):208-15.

Barros Galvao SC, et al. Efficacy of coupling repetitive transcranial magnetic stimulation and physical therapy to reduce upper-limb spasticity in patients with stroke: a randomized controlled trial. Arch Phys Med Rehabil 2014 Feb;95(2):222-9.

Benninger DH, et al. Controlled study of 50-Hz repetitive transcranial magnetic stimulation for the treatment of Parkinson disease. Neurorehabil Neural Repair 2012 Nov-Dec;26(9):1096-1105.

*Berlim MT, et al. High frequency repetitive transcranial magnetic stimulation as an augmenting strategy in severe treatment-resistant major depression: a prospective 4-week naturalistic trial. J Affect Disord 2011 Apr;130(1-2):312-7.

Berlim MT, et al. High-frequency repetitive transcranial magnetic stimulation accelerates and enhances the clinical response to antidepressants in major depression: a meta-analysis of randomized, double-blind, and sham-controlled trials. J Clin Psychiatry 2013 Feb;74(2):e122-9.

Berlim MT, et al. Response, remission and drop-out rates following high-frequency repetitive transcranial magnetic stimulation (rTMS) for treating major depression: a systematic review and meta-analysis of randomized, double-blind and sham-controlled trials. Psychol Med 2014 Jan;44(2):225-39.

Berlim MT, et al. Clinically meaningful efficacy and acceptability of low-frequency repetitive transcranial magnetic stimulation (rTMS) for treating primary major depression: a meta-analysis of randomized, double-blind and sham-controlled trials. Neuropsychopharmacology 2013 Mar;38(4):543-51.

Berlim MT, et al. Efficacy and acceptability of high frequency repetitive transcranial magnetic stimulation (rTMS) versus electroconvulsive therapy (ECT) for major depression: a systematic review and meta-analysis of randomized trials. Depress Anxiety 2013 Jul;30(7):614-23.

Bersani FS, et al. Deep transcranial magnetic stimulation as a treatment for psychiatric disorders: a comprehensive review. Eur Psychiatry 2013 Jan;28(1):30-9.

*BlueCross BlueShield Association. Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. 2009 Oct;24(5).

BlueCross BlueShield Association. Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. 2011 Nov;26(6).

BlueCross BlueShield Association. Technology Evaluation Center (TEC). Transcranial magnetic stimulation for depression. 2013;28(9).

BlueCross BlueShield Association. Technology Evaluation Center (TEC). Transcranial magnetic stimulation for schizophrenia. 2011 Nov;26(6).

BlueCross BlueShield Association. Transcranial Magnetic Stimulation as a treatment of depression and other psychiatric/neurologic Disorders. Medical Policy Reference Manual Policy # 2.01.50. 2017 July 13.

*Boggio PS, et al. Noninvasive brain stimulation with high frequency and low intensity repetitive transcranial magnetic stimulation treatment for posttraumatic stress disorder. J Clin Psychiatry 2010 Aug;71(8):992-9.

Boyer L, et al. rTMS in fibromyalgia: a randomized trial evaluating QoL and its brain metabolic substrate. Neurology 2014 Apr 8;82(14):1231-38.

Brunoni AR, et al. Repetitive transcranial magnetic stimulation for the acute treatment of major depressive episodes: a systematic review with network meta-analysis. JAMA Psychiatry 2017 Feb 1;74(2):143-152.

Chen R, et al. Transcranial magnetic stimulation for the treatment of epilepsy. Cochrane database Syst Rev 2016 Aug 11;(8):CD011025.

Chistyakov AV, et al. Preliminary assessment of the therapeutic efficacy of continuous theta-burst magnetic stimulation (cTBS) in major depression: a double-blind sham-controlled study. J Affect Disord 2015 Jan 1;170:225-9.

Chou YH, et al. Effects of repetitive transcranial magnetic stimulation on motor symptoms in Parkinson disease: a systematic review and meta-analysis. JAMA Neurol 2015 April;72(4):432-440.

Chung, et al. Effect of repetitive transcranial magnetic stimulation on physical function and motor signs in Parkinson's disease: systematic review and meta-analysis. Brain Stimul 2016 July-Aug;9(4):475-487.

Connolly KR, et al. Effectiveness of transcranial magnetic stimulation in clinical practice post-FDA approval in the United States: results observed with the first 100 consecutive cases of depression at an academic medical center. J Clin Psychiatry 2012 Apr;73(4):e567-73.

*Couturier JL. Efficacy of rapid-rate repetitive transcranial magnetic stimulation in the treatment of depression: a systematic review and meta-analysis. J Psychiatry Neurosci 2005 Mar;30(2):83-90.

Cristancho MA, et al. Transcranial magnetic stimulation maintenance as a substitute for maintenance electroconvulsive therapy: a case series. J ECT 2013 Jun;29(2):106-8.

*Dell'Osso B, et al. Augmentative repetitive navigated transcranial magnetic stimulation (rTMS) in drug-resistant bipolar depression. Bipolar Disord 2009 Feb;11(1):76-81.

Dinur-Klein L, et al. Smoking cessation induced by deep repetitive transcranial magnetic stimulation of the prefrontal and insular cortices: a prospective, randomized controlled trial. Biol Psychiatry 2014 Nov 1;76(9):742-749.

*Dlabac-de Lange JJ, et al. Repetitive transcranial magnetic stimulation for negative symptoms of schizophrenia: review and meta-analysis. J Clin Psychiatry 2010 Apr;71(4):411-8.

Dlabac-deLange JJ, et al. Efficacy of bilateral repetitive transcranial magnetic stimulation for negative symptoms of schizophrenia: results of a multicenter double-blind randomized controlled trial. Psychol Med 2015 April;45(6):1263-1275.

Dougall N, et al. Transcranial magnetic stimulation for schizophrenia. Schizophr Bull 2015 Nov;41(6):1220-1222.

Du J, et al. Repetitive transcranial magnetic stimulation for rehabilitation of poststroke dysphagia: a randomized, double-blind clinical trial. Clin Neurophysiol 2016 March;127(3):1907-1913.

Dunner DL, et al. A multisite, naturalistic, observational study of transcranial magnetic stimulation (TMS) for patients with pharmacoresistant major depression: Durability of benefit over a one-year follow-up period. J Clin Psychiatry 2014 [Epub ahead of print].

*Eranti S, et al. A randomized, controlled trial with 6-month follow-up of repetitive transcranial magnetic stimulation and electroconvulsive therapy for severe depression. Am J Psychiatry 2007 Jan;164(1):73-81.

*Fitzgerald PB, et al. Transcranial magnetic stimulation in the treatment of depression: a double-blind, placebo-controlled trial. Arch Gen Psychiatry 2003 Oct;60(10):1002-8.

*Fitzgerald PB, et al. A randomized, controlled trial of sequential bilateral repetitive transcranial magnetic stimulation for treatment-resistant depression. Am J Psychiatry 2006 Jan;163(1):88-94.

Fitzgerald PB, et al. An open label trial of clustered maintenance rTMS for patients with refractory depression. Brain Stim 2013 May;6(3):292-7.

Folmer RL, et al. Repetitive transcranial magnetic stimulation treatment for chronic tinnitus: a randomized clinical trial. JAMA Otolaryngol Head Neck Surg 2015 Aug;141(8):716-722.

Fricova J, et al. Repetitive transcranial magnetic stimulation in the treatment of chronic orofacial pain. Physiol Res 2013 Dec 12;62 Suppl 1:S125-34.

Galhardoni R, et al. Repetitive transcranial magnetic stimulation in chronic pain: a review of the literature. Arch Phys Med Rehabil 2015 April;96(4 Suppl):S156-172.

Gao F, et al. Repetitive transcranial magnetic stimulation for pain after spinal cord injury: a systematic review and meta-analysis. J Neurosurg Sci 2017 Oct;61(5):514-522.

Gaynes BN, et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: a systematic review and meta-analysis. J Clin Psychiatry 2014 May;75(5):477-89.

*George MS, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: a sham-controlled randomized trial. Arch Gen Psychiatry 2010 May;67(5):507-16.

*George MS. Transcranial magnetic stimulation for the treatment of depression. Expert Rev Neurother 2010 Nov;10(11):1761-72.

George MS, et al. A two-site pilot randomized 3 day trial of high dose left prefrontal repetitive transcranial magnetic stimulation (rTMS) for suicidal inpatients. Brain Stim 2014 May-Jun;7(3):421-31.

Graef P, et al. Transcranial magnetic stimulation combined with upper-limb training for improving function after stroke: a systematic review and meta-analysis. J Neurol Sci 2016 Oct 15;369:149-158.

*Gross M, eta l. Has repetitive transcranial magnetic stimulation (rTMS) treatment for depression improved? A systematic review and meta-analysis comparing the recent vs. the earlier rTMS studies. Acta Psychiatr Scand 2007 Sep;116(3):165-73.

Guo J, et al. Repetitive transcranial magnetic stimulation for the treatment of amyotrophic lateral sclerosis or motor neuron disease. Cochrane Database Rev 2011 Sep 7;(9):CD008554.

Guse B, et al. The effect of long-term high frequency repetitive transcranial magnetic stimulation on working memory in schizophrenia and healthy controls- a randomized placebo-controlled, double-blind fMRI study. Behav Brain Res 2013 Jan 15;237:300-7.

Hadley D, et al. Safety, tolerability, and effectiveness of high doses of adjunctive daily left prefrontal repetitive transcranial magnetic stimulation for treatment-resistant depression in a clinical setting. J ECT 2011 Mar;27(1):18-25.

Haghighi M, et al. Repetitive transcranial magnetic stimulation (rTMS) improved symptoms and reduces clinical illness in patients suffering from OCD—results from a single-blind, randomized clinical trial with sham cross-over condition. J Psychiatr Res 2015 Sept;68:238-244.

Health Quality Ontario. Repetitive transcranial magnetic stimulation for treatment-resistant depression: a systematic review and meta-analysis of randomized controlled trials. Ont Health Technol Assess Ser 2016 March 1;16(5):1-66.

*Herrmann LL, et al. Factors modifying the efficacy of transcranial magnetic stimulation in the treatment of depression: a review. J Clin Psychiatry 2006 Dec;67(12):1870-6.

Hsu WY, et al. Effects of repetitive transcranial magnetic stimulation on motor functions in patients with stroke: a meta-analysis. Stroke 2012 Jul;43(7):1849-57.

*Herwig, et al. Antidepressant effects of augmentative transcranial magnetic stimulation: randomized multicentre trial. Br J Psychiatry 2007 Nov;191:441-8.

Hovington CL, et al. Repetitive transcranial magnetic stimulation (rTMS) for treating major depression and schizophrenia: a systematic review of recent meta-analyses. Ann Med 2013 Jun;45(4):308-21.

Institute for Clinical and Economic Review. The New England Comparative Effectiveness Public Advisory Council. Coverage policy analysis: Repetitive transcranial magnetic stimulation (rTMS). 2011 Dec [http://cepac.icer-review.org/wp-content/uploads/2011/04/rTMS-Coverage-Policy-Analysis.pdf] accessed 11/14/17.

*Janicak PG, et al. Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study. Brain Stimul 2010 Oct;3(4):187-99.

Jin Y, et al. High frequency repetitive transcranial magnetic stimulation therapy for chronic neuropathic pain: a meta-analysis. Pain Physician 2015 Nov;18(6):E1029-1046.

Kedzior KK, et al. Durability of the antidepressant effect of the high-frequency repetitive transcranial magnetic stimulation (rTMS) in the absence of maintenance treatment in major depression: a systematic review and meta-analysis of 16 double-blind, randomized, sham-controlled trials. Depress Anxiety 2015 March;32(3):193-203.

Kedzior KK, et al. Deep transcranial magnetic stimulation (DTMS) in the treatment of major depression: an exploratory systematic review and meta-analysis. J Affect Disord 2015 Nov 15;187:73-83.

Kedzior KK, et al. Acute reduction in anxiety after deep transcranial magnetic stimulation (DTMS) in unipolar major depression- a systematic review and meta-analysis. Psychiatry Res 2015 Dec 30;230(3):971-974.

Kedzior KK, et al. Cognitive functioning and deep transcranial magnetic stimulation (DTMS) in major psychiatric disorders: a systematic review. J Psychiatr Res 2016 April;75:107-115.

Kelly MS, et al. Initial response to transcranial magnetic stimulation treatment for depression predicts subsequent response. J Neuropsychiatry Clin Neurosci 2017 Spring;29(2):179-182.

Keshtkar M, et al. Repetitive transcranial magnetic stimulation versus electroconvulsive therapy for the treatment of major depressive disorder, a randomized controlled clinical trial. J ECT 2011 Dec;27(4):310-4.

Khedr EM, et al. Repetitive transcranial magnetic stimulation in neuropathic pain secondary to malignancy: a randomized clinical trial. Eur J Pain 2015 April;19(4):519-527.

*Kim BR, et al. Effect of repetitive transcranial magnetic stimulation on cognition and mood in stroke patients: a double-blind, sham-controlled trial. Am J Phys Med Rehabil 2010 May;89(5):662-8.

Kim BR, et al. Effect of high-and low-frequency repetitive transcranial magnetic stimulation on visuospatial neglect in patients with acute stroke: a double-blind, sham-controlled trial. Arch Phys Med Rehabil 2013 May;94(5):803-7.

Knijnik LM, et al. Repetitive transcranial magnetic stimulation for fibromyalgia: systematic review and meta-analysis. Pain Pract 2016 March;16(3):294-304.

*Koenigs M, et al. Bilateral frontal transcranial direct current stimulation: failure to replicate classic findings in healthy subjects. Clin Neurophysiol 2009 Jan;120(1):80-4.

Kwon HJ, et al. 1-Hz low frequency repetitive transcranial magnetic stimulation in children with Tourette's syndrome. Neurosci Lett 2011 Mar 29;492(1):1-4.

Le Q, et al. Effects of repetitive transcranial magnetic stimulation on hand function recovery and excitability of the motor cortex after stroke: a meta-analysis. Am J Phys Med Rehabil 2014 May;93(5):422-30.

Lefaucheur JP, et al. Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation (rTMS). Clin Neurophysiol 2014 Nov;125(11):2150-206.

Levkovitz Y, et al. Efficacy and safety of deep transcranial magnetic stimulation for major depression: a prospective multicenter randomized controlled trial. World Psychiatry 2015 Feb;14(1):64-73.

Li H, et al. Repetitive transcranial magnetic stimulation (rTMS) for panic disorder in adults (review). Cochrane Database Syst Rev 2014;9:CD009083.

Li Y, et al. Low-frequency repetitive transcranial magnetic stimulation for patients with aphasia after stroke: a meta-analysis. J Rehabil Med 2015 Sept;47(8):675-681.

*Lipton RB, et al. Single-pulse transcranial magnetic stimulation for acute treatment of migraine with aura: a randomised, double-blind, parallel-group, sham-controlled trial. Lancet Neurol 2010 Apr;9(4):373-80.

Liu B, et al. Repetitive transcranial magnetic stimulation as a augmentative strategy for treatment-resistant depression, a meta-analysis of randomized, double-blind and sham controlled study. BMC Psychiatry 2014 Nov 30;14:342.

Loo CK, et al. Transcranial direct current stimulation for depression: 3-week, randomized, sham-controlled trial. Br J Psychiatry 2012 Jan;200(1):52-9.

*Mantovani A, et al. Randomized sham-controlled trial of repetitive transcranial magnetic stimulation in treatment-resistant obsessive-compulsive disorder. Int J Neuropsychopharmacol 2010 Mar;13(2):217-27.

Mantovani A, et al. Randomized sham controlled trial of repetitive transcranial magnetic stimulation to the dorsolateral prefrontal cortex for the treatment of panic disorder with comorbid major depression. J Affect Disord 2013 Jan 10;144(1-2):153-9.

Mantovani A, et al. Long-term efficacy of repeated daily prefrontal transcranial magnetic stimulation (TMS) in treatment-resistant depression. Depress Anxiety 2012 Oct;29(10):883-90.

Marlow NM, et al. Efficacy of transcranial direct stimulation and repetitive transcranial magnetic stimulation for treating fibromyalgia syndrome: a systematic review. Pain Pract 2013 Feb;13(2):131-45.

*Martin JL, et al. Transcranial magnetic stimulation for the treatment of obsessive-compulsive disorder. Cochrane Database Syst Rev 2003;(3):CD003387.

*Matheson SL, et al. Quality assessment and comparison of evidence for electroconvulsive therapy and repetitive transcranial magnetic stimulation for schizophrenia: a systematic meta-review. Schizophr Res 2010 May;118(1-3):201-10.

Mayer G, et al. Repetitive transcranial magnetic stimulation in depressed adolescents. J ECT 2012 Jun;28(2):104-7.

Mayer G, et al. Long-term follow-up of adolescents with resistant depression treated with repetitive transcranial magnetic stimulation. J ECT 2012 Jun;28(2):84-6.

McGirr A, et al. Effectiveness and acceptability of accelerated repetitive transcranial magnetic stimulation (rTMS) for treatment-resistant major depressive disorder: an open label trial. J Affect Disord 2015 Mar 1;173:216-20.

McIntyre A, et al. Repetitive transcranial magnetic stimulation for depression due to cerebrovascular disease: a systematic review. J Stroke Cerebrovasc Dis 2016 Dec;25(12):2792-2800.

*McLoughlin DM, et al. The clinical effectiveness and cost of repetitive transcranial magnetic stimulation versus electroconvulsive therapy in severe depression: a multicentre pragmatic randomized controlled trial and economic analysis. Health Technol Assess 2007 Jul;11(24):1-54.

Minichino A, et al. ECT, rTMS, and deep TMS in pharmacoresistant drug-free patients with unipolar depression: a comparative review. Neuropsychiatr Dis Treat 2012;8:55-64.

Misra UK, et al. High-rate repetitive transcranial magnetic stimulation in migraine prophylaxis: a randomized, placebo-controlled study. J Neurol 2013 Nov;260(11):2793-801.

National Institute for Health and Clinical Excellence. Transcranial magnetic stimulation for depression. IPG 542. Dec 2015 [nice.org.uk/guidance/ipg542] accessed 11/14/17..

National Institute for Health and Clinical Excellence. Transcranial magnetic stimulation for treating and preventing migraine. IPG 477. Jan 2014 [http://www.nice.org.uk/guidanceipg477] accessed 11/14/17.

Noda Y, et al. Neurobiological mechanisms of repetitive transcranial magnetic stimulation of the dorsolateral prefrontal cortex in depression: a systematic review. Psychol Med 2015 Dec;45(16):3411-3432.

O'Connell NE, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev 2014 Apr 11;4:CD008208.

Onesti E, et al. H-coil repetitive transcranial magnetic stimulation for pain relief in patients with diabetic neuropathy. Eur J Pain 2013 Oct;17(9):1347-56.

*O'Reardon JP, et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial. Biol Psychiatry 2007 Dec 1;62(11):1208-16.

*Pal E, et al. The impact of left prefrontal repetitive transcranial magnetic stimulation on depression in Parkinson's disease: a randomized, double-blind, placebo-controlled study. Mov Disord 2010 Oct 30;25(14):2311-7.

Peng Z, et al. Effectiveness of repetitive transcranial magnetic stimulation for chronic tinnitus: a systematic review. Otolaryngol Head Neck Surg 2012 Nov;147(5):817-25.

Pereira LS, et al. Safety of repetitive transcranial magnetic stimulation in patients with epilepsy: a systematic review. Epilepsy Behav 2016 April;57(Pt A):167-176.

Perera T, et al. The Clinical TMS Society consensus review and treatment recommendations for TMS therapy for major depressive disorder. Brain Stimul 2016 May-June;9(3):336-346.

Philip NS, et al. 5Hz repetitive transcranial magnetic stimulation to left prefrontal cotex for major depression. J Affect Disord 2015 Nov 1;186:13-17.

Philip NS, et al. 5-Hz transcranial magnetic stimulation for comorbid posttraumatic stress disorder and major depression. J Trauma Stress 2016 Feb;29(1):93-96.

Philip NS, et al. Can medication free, treatment-resistant, depressed patients who initially respond to TMS be maintained off medications? A prospective, 12-month multisite randomized pilot study. Brain Stimul 2016 March-April;9(2):251-257.

Prikryl R, et al. Can repetitive transcranial magnetic stimulation be considered effective treatment option for negative symptoms of schizophrenia? J ECT 2013 Mar;29(1):67-74.

Quan WX, et al. The effects of high- frequency repetitive transcranial magnetic stimulation (rTMS) on negative symptoms of schizophrenia and the follow-up study. Neurosci Lett 2015 Jan 1;584:197-201.

Rabey JM, et al. Repetitive transcranial magnetic stimulation combined with cognitive training is a safe and effective modality for the treatment of Alzheimer's disease: a randomized, double-blind study. J Neural Transm 2013 May;120(5):813-9.

Rapinesi C, et al. Maintenance deep transcranial magnetic stimulation sessions are associated with reduced depressive relapses in patients with unipolar or bipolar depression. Front Neurol 2015 Feb 9;6:16.

*Rasmussen KG. Some considerations in choosing electroconvulsive therapy versus transcranial magnetic stimulation for depression. J ECT 2011 Mar;27(1):51-4.

Ren J, et al. Repetitive transcranial magnetic stimulation versus electroconvulsive therapy for major depression: a systematic review and meta-analysis. Prog Neuropsychopharm Biol Psychiatry 2014 Jun 3;51:181-9.

Richieri R, et al. Maintenance transcranial magnetic stimulation reduces depression relapse: a propensity analysis. J Affect Disord 2013 Oct;151(1):129-35.

*Rodriguez-Martin JL, et al. Transcranial magnetic stimulation for treating depression 2003 review. The Cochrane Collaboration Cochrane Library 2009 Issue 1.

Rosenberg O, et al. Long-term follow-up of MDD patients who respond to deep rTMS: a brief report. Isr J Psychiatry Relat Sci 2015;52(1):17-23.

*Sachdev PS, et al. Repetitive transcranial magnetic stimulation for the treatment of obsessive compulsive disorder: a double-blind controlled investigation. Psychol Med 2007;37(11):1645-9.

Saltychev M, et al. Effectiveness of repetitive transcranial magnetic stimulation in patients with fibromyalgia: a meta-analysis. Int J Rehabil Res 2017 March;40(1):11-18.

Sayar GH, et al. Transcranial magnetic stimulation for treating depression in elderly patients. Neuropsychiatry Dis Treat 2013;9:501-4.

Seniow J, et al. Transcranial magnetic stimulation combined with physiotherapy in rehabilitation of poststroke hemiparesis: a randomized, double-blind, placebo-controlled study. Neurorehabil Neural Repair 2012 Nov-Dec;26(9):1072-9.

Serafini G, et al. The effects of repetitive transcranial magnetic stimulation on cognitive performance in treatment-resistant depression. A systematic review. Neuropsychobiology 2015;71(3):125-139.

Shin HW, et al. Effect of high-frequency repetitive transcranial magnetic stimulation on major depressive disorder in patients with Parkinson's disease. J Neurol 2016 July;263(7):1442-1448.

Silverstein WK, et al. Neurobiological predictors of response to dorsolateral prefrontal cortex repetitive transcranial magnetic stimulation in depression: a systematic review. Depress Anxiety 2015 Dec;32(12):871-891.

*Slotema CW, et al. Should we expand the toolbox of psychiatric treatment methods to include repetitive Transcranial Magnetic Stimulation (rTMS)? A meta-analysis of the efficacy of rTMS in psychiatric disorders. J Clin Psychiatry 2010 Jul;71(7):873-84.

Slotema CW, et al. Meta-analysis of repetitive transcranial magnetic stimulation in the treatment of auditory verbal hallucinations: update and effects after one month. Schizophr Res 2012 Dec;142(1-3):40-5.

Speer AM, et al. Antidepressant efficacy of high and low frequency rTMS at 110% of motor threshold versus sham stimulation over left prefrontal cortex. Brain Stimul 2014 Jan-Feb;7(1):36-41.

*Stern WM, et al. Antidepressant effects of high and low frequency repetitive transcranial magnetic stimulation to the dorsolateral prefrontal cortex: a double-blind, randomized, placebo-controlled trial. J Neuropsychiatry Clin Neurosci 2007 Spring;19(2):179-86.

Sun W, et al. Low-frequency repetitive transcranial magnetic stimulation for treatment of refractory partial epilepsy: a controlled clinical study. Epilepsia 2012 Oct;53(10):1782-9.

Tang Q, et al. A systematic review for the antidepressant effects of sleep deprivation with repetitive transcranial magnetic stimulation. BMC Psychiatry 2015 Nov 14;15:282.

Tarhan N, et al. Efficacy of high-frequency repetitive transcranial magnetic stimulation in treatment-resistant depression. Clin EEG Neurosci 2012 Oct;43(4):279-84.

Theleritis C, et al. Two versus one high-frequency repetitive transcranial magnetic stimulation session per day for treatment-resistant depression: a randomized sham-controlled trial. J ECT 2017 Sept;33(3):190-197.

Trevizol AP, et al. Transcranial magnetic stimulation for obsessive-compulsive disorder: an updated systematic review and meta-analysis. J ECT 2016 Dec;32(4):262-266.

Trevizol AP, et al. Transcranial magnetic stimulation for posttraumatic stress disorder: an updated systematic review and meta-analysis. Trends Psychiatry Psychother 2016 Jan-Mar;38(1):50-55.

Trojak B, et al. Transcranial magnetic stimulation combined with nicotine replacement therapy for smoking cessation: a randomized controlled trial. Brain Stimul 2015 Nov-Dec;8(6):1168-1174.

Ullrich H, et al. Ultra-high-frequency left prefrontal transcranial magnetic stimulation as augmentation in severely ill patients with depression: a naturalistic sham-controlled, double-blind, randomized trial. Neuropsychobiology 2012;66(3):141-8.

Wang H, et al. Efficacy of repetitive transcranial magnetic stimulation in the prevention of relapse of depression: study protocol for a randomized controlled trial. Trials 2013 Oct 17;14:338.

Xie J, et al. Repetitive transcranial magnetic stimulation versus electroconvulsive therapy for major depression: a meta-analysis of stimulus parameter effects. Neurol Res 2013 Dec;35(10):1084-91.

Xie CL, et al. Repetitive transcranial magnetic stimulation (rTMS) for the treatment of depression in Parkinson disease: a meta-analysis of randomized controlled clinical trials. Neurol Sci 2015 Oct;36(10):111111751-1761.

Yan T, et al. Different frequency repetitive transcranial magnetic stimulation (rTMS) for posttraumatic stress disorder (PTSD): a systematic review and meta-analysis. J Psychiatry Res 2017 June;89:125-135.

Yang YR, et al. Combination of rTMS and treadmill training modulates corticomotor inhibition and improves walking in Parkinson disease: a randomized trial. Neurorehabil Neural Repair 2013 Jan;27(1):79-86.

*Yukimasa T, et al. High-frequency repetitive transcranial magnetic stimulation improves refractory depression by influencing catecholamine and brain-deprived neurotrophic factors. Pharmacopsychiatry 2006 Mar;39(2):52-9.

Zhou DD, et al. An updated meta-analysis: short-term therapeutic effects of repeated transcranial magnetic stimulation in treating obsessive-compulsive disorder. J Affect Disord 2017 June;215:187-196.

* key article

KEY WORDS:

Brainsway Deep TMS, MagVita TMS, NeuroStar, rTMS, Transcranial magnetic therapy, TMS.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for transcranial magnetic stimulation. Please refer to the following LCD (L33398) website for Medicare Members:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33398&ContrId=298&ver=4&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAAAAAAA%3d%3d&