Medical Policy

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Title: Transcranial Magnetic Stimulation (TMS) as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Related Policies:	▪ *Vagus Nerve Stimulation*

Professional / Institutional
Original Effective Date: November 1, 2011
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Populations	Interventions	Comparators	Outcomes
Individuals: • With treatment-resistant depression	Interventions of interest are: • Transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy • Psychological and behavioral therapy • Electroconvulsive therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

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Populations	Interventions	Comparators	Outcomes
Individuals: • With psychiatric or neurologic disorders other than depression, migraine or obsessive-compulsive disorder	Interventions of interest are: • Transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy • Therapy as appropriate including either physical and occupational therapy or psychological and behavioral therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With obsessive-compulsive disorder	Interventions of interest are: • Transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy • Psychological and behavioral therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life
Individuals: • With migraine	Interventions of interest are: • Transcranial magnetic stimulation	Comparators of interest are: • Pharmacotherapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life

DESCRIPTION

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 the passing of 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.

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.

BACKGROUND

Transcranial Magnetic Stimulation

Transcranial magnetic stimulation (TMS), introduced in 1985 as a new method of noninvasive stimulation of the brain, involves placement of a small coil over the scalp, passing a rapidly alternating current through the coil wire, which produces a magnetic field that passes unimpeded

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through the scalp and bone, resulting in electrical stimulation of the cortex. Transcranial magnetic stimulation was initially used to investigate nerve conduction (eg, TMS over the motor cortex will produce a contralateral muscular-evoked potential). The motor threshold, which is the minimum intensity of stimulation required to induce a motor response, is empirically determined for each person by localizing the site on the scalp for optimal stimulation of a hand muscle, then gradually increasing the intensity of stimulation. Interest in the use of TMS as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation. Imaging studies had shown a decrease in the activity of the left dorsolateral prefrontal cortex in depressed patients, and early studies suggested that high-frequency (eg, 5 to 10 Hz) TMS of the left dorsolateral prefrontal cortex had antidepressant effects. In contrast to electroconvulsive therapy (ECT), TMS does not require general anesthesia and does not generally induce a convulsion. Repetitive TMS (rTMS) is also being tested as a treatment for a variety of other psychiatric and neurologic disorders.

Conventional TMS delivers repeated electromagnetic pulses to induce prolonged modulation of neural activity, typically applied over the dorsolateral prefrontal cortex. High-frequency rTMS (usually ≥10 Hz) induces an increase in neural activity whereas low-frequency TMS (usually ≤1 Hz) has the opposite effect. If both procedures are performed in the same session, the intervention is described as bilateral rTMS.

A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation. Deep TMS employs an H-coil helmet design to encompass a broader surface area and stimulate deeper brain structures than conventional TMS. Theta burst stimulation is administered at lower intensities and shorter intervals than conventional rTMS. Navigated TMS integrates electromagnetic stimulation with MRI-based neuronavigation to individualize coil placement over specific cortical targets.

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.

The Nexstim Navigated Brain Therapy System 2 received FDA 510(k) 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 in 2017 (K171902), with an intermittent theta burst stimulation protocol subsequently added in 2019 (K182700). In 2026, the Navigated Brain Stimulation System 6 received clearance as an adjunct for the treatment of major depressive disorder in adolescent patients aged 15 to 21 years (K252358) and as an adjunct for the treatment of obsessive-compulsive disorder in adults (K253098).

The FDA has cleared multiple rTMS systems for adjunctive treatment of major depressive disorder in adolescents aged 15 to 21, including the NeuroStar Advanced Therapy System (K231926), the Magstim Horizon (K243869), the MagVenture (K251125) stimulators, and the Nexstim Navigated Brain Stimulation System 6 (K252358).

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 Transcranial Magnetic Stimulation Devices Cleared by the U.S. Food and Drug Administration for Major Depression, Migraine, or Obsessive-Compulsive Disorder

Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
Brainsway SWIFT™	Brainsway Ltd.	Major Depressive Disorder	K251449	08/16/2025
Magnus Neuromodulation System (MNS) with SAINT Technology	Magnus Medical, Inc.	Major Depressive Disorder	K220177	09/01/2022
MagVenture TMS Therapy System	Tonica Elektronik	Major depressive disorder and obsessive-compulsive disorder	K193006	08/09/2020
Ultimate rTMS for OCD (M-series)	Brain Ultimate, Inc.	Major depressive disorder and obsessive-compulsive disorder	K230735	09/13/2023
CloudTMS Edge for OCD	TeleEMG, LLC	Obsessive-Compulsive Disorder	K233742	12/22/2023
Savi Dual™ Migraine Therapy	ENeura	Migraine (acute and prophylactic treatment in individuals ≥12 years of age)	K230358	05/16/2023
Horizon 3.0 TMS Therapy System	Magstim	Major depressive disorder and obsessive-compulsive disorder	K222171	01/13/2023
ALTMS Magnetic Stimulation Therapy System	REMED Co., Ltd	Major depressive disorder	K220625	04/06/2022
Neurostar	Neuronetics	Major Depressive Disorder	K083538	12/16/2008
		Obsessive-Compulsive Disorder	K212289	05/06/2022

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Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
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 Navigated Brain Therapy System	Nexstim Plc	Major Depressive Disorder	K171902	11/10/2017
Nexstim Navigated Brain Therapy System (Intermittent Theta Burst Protocol)	Nexstim Plc	Major Depressive Disorder	K182700	03/22//2019
Navigated Brain Stimulation System 6	Nexstim Plc	Major Depressive Disorder	K252358	03/20/2026

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Device	Manufacturer	Indication	FDA Clearance No.	FDA Clearance Date
Navigated Brain Stimulation System 6	Nexstim Plc	Obsessive-Compulsive Disorder	K253098	03/20/2026
Apollo	Mag & More	Major Depressive Disorder	K180313	05/04/2018

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POLICY

A. Transcranial magnetic stimulation (rTMS) 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 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. 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:
         i. The trial length was at least 6 weeks at generally accepted doses; **AND**
         ii. Individual was ≥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 response to rTMS 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 rTMS (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized).

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

C. Continued treatment with rTMS of the brain as maintenance therapy is considered **experimental / investigational**.

D. Transcranial magnetic stimulation of the brain is considered **experimental / investigational** as a treatment of all other psychiatric/neurologic disorders including, but not limited to, bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches.

POLICY GUIDELINES

A. Transcranial magnetic stimulation (TMS) should be performed using a U.S. Food and Drug Administration cleared device in appropriately selected individuals over age 15 years, by health care professionals who are adequately trained and experienced in the specific techniques used.

B. The physician is responsible for the initial mapping (once per course or delivery) and the management of the treatment. The physician is also responsible for the re-determinations.

C. A trained technician may perform the subsequent delivery of treatment.

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D. A variety of TMS modalities have been developed, which differ on parameters including stimulation intensity, frequency, pattern, and site of the brain stimulation.

E. 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.

F. Theta burst stimulation is administered at lower intensities and at shorter intervals than conventional TMS.

G. Deep TMS employs an H-coil helmet designed to encompass a broader surface area and stimulate deeper brain structures than conventional TMS.

H. A treatment course should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 TMS treatments in week one, 2 TMS treatments the next week, and 1 TMS treatment in the last week.

I. 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 another is the Brainsway SWIFT protocol, consisting of 5 daily sessions for 6 days using standard H1-coil positioning without neuroimaging (K251449, September 2025). It is not established whether fMRI-guided targeting confers incremental benefit over standard coil placement in accelerated protocols, and long-term durability data are limited.

J. 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 (e.g., 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.

K. 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 times; and
   2. Adequate resuscitation equipment including, e.g., 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.

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RATIONALE

This evidence review was created using searches of the PubMed database. The most recent literature update was performed through May 9, 2026.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

TREATMENT-RESISTANT DEPRESSION

Clinical Context and Therapy Purpose

The purpose of repetitive transcranial magnetic stimulation (rTMS) is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with treatment-resistant depression (TRD).

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with TRD.

Interventions

The therapy being considered is rTMS.

Comparators

The following therapies are currently being used to treat TRD: pharmacotherapy, psychological and behavioral therapy, and electroconvulsive therapy (ECT).

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Outcomes

The general outcomes of interest are reductions in symptoms and improvements in quality of life and functional outcomes.

Table 2. Health Outcome Measures Relevant to Treatment-Resistant Depression, Major Depressive Disorder, Suicidal Ideation, and Suicidal Behavior

Outcome	Description	Scale	Clinically Meaningful Difference
MADRS	• Physician scored • Rates presence and severity of depression • Symptom domains include sadness; pessimism; inability to feel; suicidality	• Contains 10 items (scored from 0 to 6) with higher scores indicating more severe depression • No validated cut-off score but generally 0 to 6 normal (no depression); 7 to 19 mild depression; 20 to 34 moderate depression; 35 to 59 severe depression; 60 or greater very severe depression1,	• No consensus to define remission. Thresholds for remission have ranged from 6 to 12 in trials. • One literature review reported that the mean weighted MADRS score for remission was 4.0 (95% CI, 3.5-4.5) based on 10 studies.2, The definition of remission was a complete absence of clinically significant symptoms of depression. • As per FDA, for drugs that have been approved to treat MDD as monotherapy or adjunctive treatment, treatment differences were typically closer to 3 or 4 points in MADRS scores. The observed treatment differences in esketamine studies were in that range.3,
HAM-D	• Physician scored • Rates presence and severity of depression • Used in a number of registration studies of approved oral antidepressants • Symptom domains include sadness; pessimism; inability to feel; suicidality	• There are 2 versions: 17 or 25 items; 17 items is more common • Each item scored in a range of 0 to 2 or 0 to 4, with higher scores indicating a greater degree of depression • Scores range from 0 to 48 • Scores as low as 17 are associated with	• Remission is defined as total score of 7 or less. But 2 or less has been suggested as optimal. • Response to treatment is defined as a 50% reduction from baseline scores.

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Outcome	Description	Scale	Clinically Meaningful Difference
		moderate depression and those at or above 24 are associated with severe depression2,	
SIBAT	• Contains both patient- and clinician-reported modules and can be assessed by patient or rated by the physician • Includes assessments of ○ Severity of Suicidality (CGI-SS-r) ○ Imminent Suicide Risk (CGI-SR-I) ○ Frequency of Suicidal Thinking (FoST)[4,]	• CGI-SS-r: rated from 0 (normal, not at all suicidal) to 6 (among the most extremely suicidal patients) • CGI-SR-I: rates best clinical judgment of participant's imminent risk for suicide within the next 7 days. Scale indicates: 0 (No imminent suicide risk), 1 (Minimal imminent), 2 (Mild imminent), 3 (Moderate imminent), 4 (Marked imminent), 5 (Severely imminent), 6 (Extreme imminent). • FoST: describes the clinician determined estimate of the frequency of the participant's suicidal thinking. Scored on a 6-point Likert scale: 0 (Never), 1 (Rarely), 2 (Sometimes), 3 (Often), 4 (Most of the time), 5 (All of the time).[4,]	• No literature was identified for a consensus definition for a clinically meaningful change in scores

CGI-SR-I: Clinical Global Impression of Imminent Suicide Risk Scale, CGI-SS-r: Clinical Global Impression of Severity of Suicidality-Revised, CI: confidence interval; FDA: U.S. Food and Drug Administration; FoST: Frequency of Suicidal Thinking, HAM-D: Hamilton Rating Scale for Depression, MADRS: Montgomery-Asberg Depression Rating Scale, MDD: major depressive disorder; SIBAT: Suicide Ideation and Behavior Assessment Tool.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

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- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Evaluation of rTMS for TRD includes RCTs comparing rTMS with sham as well as evidence when used as a replacement for or adjunct to pharmacotherapy that has not improved depressive symptoms. In addition, evaluation of rTMS in TRD includes the use of rTMS as an alternative to ECT. However, some individuals may not elect ECT due to its requirement for general anesthesia and induction of seizures.

There has been a trend to use rTMS at increased levels of intensity, trains of pulses, total pulses per session, and the number of sessions.[5,] Unless otherwise indicated, stimulation was set at 100% to 120% of motor threshold, clinical response was defined as an improvement of 50% or more on the Hamilton Rating Scale for Depression (HAM-D), and remission was considered to be a score of 7 or less on the HAM-D. Refer to the meta-analysis by Schutter (2009) for a summary of study characteristics and stimulation parameters used in trials conducted prior to 2008.[6,]

Systematic Reviews
In pediatric major depressive disorder, Gallop et al identified 28 studies (n=640 participants), including 4 double-blind, sham-controlled RCTs, 1 additional trial which compared low-frequency vs. high-frequency rTMS, 6 open-label cohort studies, and multiple case reports.[7,] The largest RCT (n=103) found no significant difference between active and sham rTMS on clinician-rated depression severity or remission rates, while another RCT (n=100) showed that rTMS combined with a selective serotonin reuptake inhibitor (SSRI) produced significantly greater reductions in HAM-D, children's depression rating scale-revised (CDRS-R) scores, and higher response rates than SSRI alone. A smaller sham-controlled RCT (n=55) reported reductions in depression severity and fewer self-injury impulses in non-medicated adolescents who received rTMS. Open-label cohorts (n=8 to 32) generally reported significant reductions in both clinician-rated and self-reported depression severity, with some effects maintained up to 6 months. A meta-analysis was not performed due to heterogeneity in study design, comparators, and stimulation protocols.

The Health Quality Ontario (2016) published a systematic review of left dorsolateral prefrontal cortex (DLPFC) rTMS for TRD.[8,] Reviewers included 23 RCTs (n=1156 patients) that compared rTMS with sham and 6 RCTs (n=266 patients) that compared rTMS with ECT. In 16 studies, patients received rTMS in addition to antidepressant medication. Seven studies used intensities of less than 100% motor threshold and the definition of remission in the included studies varied (from ≤7 to ≤10 on the HAM-D). Meta-analysis showed a statistically significant improvement in depression scores compared with sham, with a weighted mean difference (WMD) of 2.31 (Table 3). However, this was smaller than the prespecified clinically important difference of 3.5 points on the HAM-D, and the effect size was small (0.33; 95% confidence interval [CI], 0.17 to 0.5; p<.001). Subgroup analysis showed a larger and clinically significant treatment effect in the rTMS studies using 20 Hz with shorter train duration compared with other rTMS techniques (WMD, 4.96; 95% CI, 1.15 to 8.76; p=.011). Secondary analyses showed rTMS demonstrated statistically greater response rates among 20 studies (pooled relative risk [RR], 1.72) as well as statistically greater remission rates among 13 studies (pooled RR, 2.20). For the 6 trials that compared rTMS with ECT, the WMD of 5.97 was both statistically and clinically significant in favor

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of ECT. The RR for remission and response rates are shown in Table 3, which while favoring ECT were not statistically significant. Remission and relapse rates at the 6-month follow-up were reported in 2 studies (n=40 and n=46 subjects) comparing rTMS with ECT. While 1 study reported a slightly higher remission rate for ECT (27.3%) than for rTMS (16.7%), the other study did not find a significant difference between ECT and rTMS for mean depression scores at 3 or 6 months, but did note relapses were less frequent for ECT. Statistical comparisons were either not significant or not available, limiting the interpretation of these findings.

Table 3. Statistical Comparisons for Depression Scores after Repetitive Transcranial Magnetic Stimulation

Comparison	Favors	WMD (95% CI)	p	RR for Remission (95% CI)	p	RR for Response (95% CI)	p
rTMS vs. sham	rTMS	2.31 (1.19 to 3.43)	<.001	2.20 (1.44 to 3.38)	.001	1.72 (1.13 to 2.62)	.01
rTMS vs. ECT	ECT	5.97 (0.94 to 11.0)	.02	1.44 (0.64 to 3.23)	.38	1.72 (0.95 to 3.11)	.07

CI: confidence interval; ECT: electroconvulsive therapy; rTMS: repetitive transcranial magnetic stimulation; RR: relative risk; WMD: weighted mean difference.

Valter et al (2024) performed a meta-analysis of high-frequency rTMS and transcranial direct current stimulation (tDCS) over the left dorsolateral prefrontal cortex for MDD, pooling 25 tDCS, 49 non-neuronavigated rTMS, and 13 neuronavigated rTMS RCTs.[9,] For the HAM-D and MADRS primary endpoint, all three stimulation methods showed superiority to sham: tDCS -2.44 (95% CI, -3.80 to -1.09; I2 = 66%), non-neuronavigated rTMS -4.33 (95% CI, -5.67 to -2.99; I2 = 79%), and neuronavigated rTMS -4.98 (95% CI, -6.42 to -3.53; I2 = 49%), each p <.01, with rTMS outperforming tDCS. Neuronavigated rTMS was compared to non-neuronavigated rTMS and the other observed no statistically distinguishable difference between groups (.65 point difference; chi-squared = 0.41, p =.52). The navigation finding rests on a between-study subgroup contrast rather than within-trial randomization, and the pooled estimate excluded several rTMS regimens (theta-burst, accelerated, and deep TMS).

Wang et al (2025) conducted a network meta-analysis comparing 3 left dorsolateral prefrontal cortex targeting methods across 63 RCTs (N=3080) of high-frequency rTMS or intermittent theta-burst stimulation (iTBS) for MDD. Both neuro-navigational (standardized mean difference [SMD], 1.19; 95% CI, 0.55 to 1.84) and "5 cm" targeting (SMD, 1.13; 95% CI, 0.79 to 1.47) produced significantly greater symptom reduction than sham, whereas F3 did not reach significance in the network estimate.[10,] Neuro-navigation ranked highest by surface under the cumulative ranking curve (SUCRA, 79.3) ahead of 5 cm (73.9) and F3 (40.1); however, no network comparison between targeting methods reached statistical significance, and the numerical advantage of neuro-navigation did not persist after adjusting for total pulse number. All active methods trended toward more adverse events than sham, significantly so for neuro-navigation (odds ratio [OR], 2.48; 95% CI, 1.02 to 5.99) and 5 cm (OR, 1.87; 95% CI, 1.27 to 2.77) but not F3 (OR, 2.13; 95% CI, 0.45 to 10.06), with neuro-navigation ranking worst on tolerability.

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Eren and Takım (2026) conducted a sham-controlled meta-analysis of 30 studies (N=1850) of prefrontal rTMS or theta burst stimulation in adults with MDD or treatment-resistant depression.[11,] Active stimulation increased response (OR, 4.78; 95% CI, 3.08 to 7.41; number needed to treat [NNT], 2.9; I2=21.9%) and remission (OR, 3.55; 95% CI, 2.06 to 6.13; NNT, 4.4; I2=34.5%), both rated high-certainty by GRADE; the pooled continuous effect on depressive symptoms was larger for theta burst stimulation but substantially more heterogeneous (Hedges g, -1.06; 95% CI, -1.41 to -0.70; I2=84.6%). Meta-regression found no significant linear dose-response relationship across stimulation frequency, intensity, pulse number, or session count, and effect sizes were larger in single-blind than double-blind trials.

Randomized Controlled Trials

The ASCERTAIN-TRD study was a 3-arm, open-label study published by Papakostas et al (2024).[12,] In this study, patients with TRD (failed ≥2 antidepressants) were randomized to augmentation with either aripiprazole or rTMS or were switched to venlafaxine XR. The study was open-label and limited to 8 weeks duration. A total of 235 individuals completed the study. MADRS response rates were numerically improved with rTMS augmentation compared with either aripiprazole augmentation or switching to venlafaxine/duloxetine (52.2% vs 38.1% and 35.8%, respectively). MADRS remission rates were also better among rTMS-treated individuals (34.2% vs 25.3% and 24.9%, respectively). MADRS score changes were significantly improved with rTMS (-17.39; p=.015) compared with switch (-13.22); however, augmentation with aripiprazole (-14.9; p=.069) was not significantly better than switch.

Theta Burst Stimulation Compared to Conventional Transcranial Magnetic Stimulation

Blumberger et al (2018) published a multicenter, randomized, noninferiority trial, Conventional Versus Theta Burst Repetitive Transcranial Magnetic Stimulation in the Treatment of Major Depressive Disorder comparing 10-Hz rTMS with intermittent theta burst stimulation (iTBS).[13], Between 2013 and 2016, 414 patients with TRD were enrolled and randomized to 4 to 6 weeks of rTMS (n=205) or iTBS (n=209). Treatment resistance was defined as the failure to tolerate 2 or more antidepressant trials of inadequate dose and duration or no clinical response to an adequate dose of an antidepressant. Patients who failed more than 3 antidepressant trials of adequate dosage were excluded from the trials. Patients could alter their medications during this trial. Treatment with conventional rTMS (37 minutes) and iTBS (3 minutes) was delivered 5 times a week for 4 to 6 weeks. The primary outcome measure was the 17-item HAM-D, for which scores for patients treated with rTMS improved by 10.1 points and scores for patients treated with iTBS improved by 10.2 points (adjusted difference, 0.103; lower 95% CI, -1.16; p=.001). Treatment with iTBS resulted in a higher self-rated intensity of pain (mean score, 3.8) than treatment with rTMS (mean score, 3.4; p=.011). Headache was the most common treatment-related adverse event for both groups (rTMS , 64% [131/204]; iTBS , 65% [136/208]). Serious adverse events were noted in patients treated with rTMS (1 case of myocardial infarction) and iTBS (1 case each of agitation, worsening suicidal ideation, worsening depression); there was no significant difference in the number of adverse events in the 2 groups. The trial lacked a treatment group with a placebo.

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Deep Transcranial Magnetic Stimulation

The RCT leading to 510(k) clearance of the Brainsway Deep TMS System in 2013 was conducted at 20 centers across the U.S. (n=13), Israel (n=4), Germany (n=2), and Canada (n=1).[14,] The trial included 229 patients with major depressive disorder who had not received benefits from 1 to 4 antidepressant trials or were intolerant of at least 2 antidepressant treatments. Using a per-protocol analysis, which excluded 31 patients who did not receive adequate TMS treatment and 17 patients who did not meet the inclusion and exclusion criteria, the RCT showed a significant benefit for both response rate (38.4% vs. 21.4%) and remission rate (32.6% vs. 14.6%). A modified intention-to-treat analysis (ITT), which excluded the 17 patients not meeting selection criteria, showed a significant benefit in both response rate (37% vs. 22.8%) and remission rate (30.4% vs. 15.8%). At the end of the maintenance period (16-week follow-up), the response rate remained significantly improved for deep TMS. Remission rates were not reported. The ITT analysis found no significant benefit of treatment at 4 or 16 weeks.

Accelerated Transcranial Magnetic Stimulation

Cole et al (2022) published a double-blind, randomized, sham-controlled trial of Stanford neuromodulation therapy (SNT), an accelerated, high-dose, fMRI-guided iTBS protocol, in adults with TRD. A total of 32 participants were randomized at the planned interim analysis; 29 who continued to meet inclusion criteria received active (n=14) or sham (n=15) SNT.[15,] The protocol individualized the left dorsolateral prefrontal cortex target using resting-state fMRI and delivered 10 iTBS sessions per day for 5 consecutive days, for 18,000 pulses per day. The primary outcome was change in MADRS score 4 weeks after treatment. At 4 weeks, the mean percent reduction in MADRS score was 52.5% in the active group versus 11.1% in the sham group. Across the 4-week follow-up period, response rates were 85.7% with active SNT and 26.7% with sham, and remission rates were 78.6% and 13.3%, respectively. No severe adverse events occurred, but headaches were more common in the active treatment group. The study was limited by its small sample size after early stopping at an interim analysis, its single-center design, and the absence of a direct comparison with standard rTMS or another active protocol.

Hanlon et al (2026) published a multicenter, blinded, randomized non-inferiority trial comparing accelerated iTBS with standard high-frequency Deep TMS using the H1-coil, supporting FDA 510(k) clearance of the BrainsWay SWIFT protocol.[16,] The accelerated protocol used standard coil positioning and did not require image-guided targeting. The accelerated iTBS group delivered 5 iTBS sessions per day for 6 days over a 14-day period, followed by 2 sessions per day once weekly for 4 weeks, with each session lasting approximately 10 minutes. A total of 104 patients with MDD were enrolled and randomized; 89 completers were included in the per-protocol primary analysis. Hamilton Depression Rating Scores (HDRS-21) decreased by 19.02 points in the accelerated group and 19.79 points in the standard group (mean difference, 0.76; p=.7783), meeting the prespecified noninferiority criterion. Response rates at 6 weeks were 87.8% and 87.5%, and remission rates were 78.0% and 87.5%, respectively. Median time to remission was significantly shorter in the accelerated group (21 days vs. 28 days; p=.0324). Application-site pain and headache were more common in the accelerated treatment group. One subject in the accelerated group withdrew due to an adverse event (jaw pain), and 1 severe migraine was reported in the standard-care group. No serious adverse events were reported. Limitations include the lack of a sham comparator, the use of a per-protocol primary analysis that excluded 15% of the randomized subjects, and the absence of long-term durability data.

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Ramos et al (2025) published a triple-blinded, sham-controlled RCT evaluating accelerated TBS stimulation for TRD.[17,] A total of 100 participants with TRD were randomized to active accelerated TBS using scalp-based targeting (n=50) or sham (n=50). The primary outcome was change in 17-item HDRS score at week 5. In the intention-to-treat analysis, the active group showed greater improvement than sham, with score reductions of 54.7% versus 31.9%, respectively, corresponding to an effect size of d=0.65 (95% CI, 0.29 to 1.00; p<.001). Response rates were 52% in the active group and 22% in the sham group (OR, 4.11; 95% CI, 1.66 to 10.13), and remission rates were 34% versus 16% (OR, 2.73; 95% CI, 1.03 to 7.24). Treatment was generally well tolerated, although treatment site pain was more frequent with active treatment; no serious adverse events were reported. The study was limited by its single-center design, modest sample size, short follow-up duration, and the absence of a direct comparison with standard rTMS or another active protocol.

Kratter et al (2026) published a double-blind, randomized, sham-controlled RCT of SNT-accelerated, high-dose, fMRI-guided iTBS protocol, in adults with TRD.[18,] A total of 53 participants with TRD were enrolled; 48 who continued to meet entry criteria were randomized to active (n=24) or sham (n=24) SNT. Participants had moderate-to-severe treatment resistance, with a mean of 4.5 lifetime adequate antidepressant failures and a mean baseline MADRS score of 27.9. At 1 month, the primary outcome of remission (MADRS ≤10) was achieved in 50.0% of active versus 20.8% of sham participants (p=.035; OR=3.8), and the secondary outcome of response (≥50% MADRS reduction) also favored active treatment (54.2% vs. 25.0%; p=.039; OR=3.5). No serious adverse events were reported, and no adverse event was significantly more common with active than sham treatment. The study was limited by its modest sample size, single-center design, limited demographic diversity, uncertain long-term durability, and the absence of comparison with conventional rTMS or another active comparator.

DURABILITY OF CONVENTIONAL TRANSCRANIAL MAGNETIC STIMULATION

Systematic Reviews

Kedzior et al (2015) examined the durability of the antidepressant effect of high-frequency rTMS on the left DLPFC in the absence of maintenance treatment.[19,] Included were 16 double-blind, sham-controlled, randomized trials (N=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 -0.48, and the effect sizes were lower in RCTs with 8 to 16 weeks of follow-up (d=-0.42) than with 1 to 4 weeks of follow-up (d=-0.54). The effect size was larger when an antidepressant medication was initiated concurrently with rTMS (5 RCTs, d=-.56) than when patients were on a stable dose of medication (9 RCTs, d=-0.43) or were unmedicated (2 RCTs, d=-0.26).

Randomized Controlled Trials

Noda et al (2025) published the MAINT-R trial, a randomized clinical trial comparing low-frequency rTMS with lithium pharmacotherapy for relapse prevention in treatment-resistant depression in Japan in individuals who had received prior acute rTMS.[20,] A total of 75 participants with TRD who had responded to an acute course of bilateral rTMS in the BEAT-D study were randomized 1:1 to receive weekly low-frequency (1 Hz) rTMS to the right DLPFC (24 sessions of 900 pulses at 120% motor threshold) or 24 weeks of lithium maintenance therapy (target blood

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level 0.4-0.6 mEq/L). All participants continued on the same dose of venlafaxine (150-225 mg/d) throughout the maintenance phase. There was no significant between-group difference in the primary outcome of baseline-adjusted MADRS scores at 24 weeks (mean difference, 0.3 points; 95% CI, -2.7 to 3.3 points; p=.84). Seven patients relapsed in each group (rTMS, 18.4%; lithium, 18.9%), and the Kaplan-Meier survival analysis showed no meaningful between-group difference in relapse-free periods (log-rank, p=.92). The lithium group experienced significantly more adverse events than the rTMS group (16 vs. 3; OR, 7.10; 95% CI, 1.84 to 27.49; p=.005), with the most common being depression, tremor, and headache. Limitations included the single-blind design, the absence of a placebo control group, conduct at only 2 sites in Japan, a sample size that limits generalizability, and the post hoc nature of the sample size estimation given the study's origin as an extension of the BEAT-D acute-phase trial.

Observational Studies

Dunner et al (2014) reported a 1-year follow-up with maintenance therapy from a large multicenter observational study (42 sites) of rTMS for patients with TRD.[21,] A total of 257 patients agreed to participate in the follow-up study of 307 who were initially treated with rTMS. Of them, 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 (36.2%) of the 257 patients who enrolled in the follow-up study received additional rTMS (mean, 16.2 sessions). Seventy-five (62.5%) of the 120 patients 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 a 1-year follow-up.

A variety of tapering schedules are being studied. For example, Richieri et al (2013) used propensity-adjusted analysis of observational data and found that patients who had rTMS tapered over 20 weeks (from 3 times per week to once a month) had a significantly reduced relapse rate than patients who had no additional treatment (37.8% vs. 81.8%).[22,] Connolly et al (2012) reported that in the first 100 cases treated at their institution, the response rate was 50.6% and the remission rate was 24.7%.[23,] At 6 months after the initial rTMS treatment, 26 (62%) of 42 patients who received tapered maintenance therapy (from 2 sessions per week for the first 3 weeks to monthly) maintained their response. In another study, Janicak et al (2010) evaluated patients who met criteria for a partial response during either a sham-controlled or an open-label phase of a prior study were tapered from rTMS and simultaneously started on maintenance antidepressant monotherapy.[24,] During the 24-week follow-up, 10 of 99 patients relapsed, 38 had symptom worsening, and of these 32 (84%) had symptomatic benefit with adjunctive rTMS.

Section Summary: Treatment-Resistant Depression

There are a large number of sham-controlled randomized trials and meta-analyses of these RCTs evaluating the use of rTMS for depression. Meta-analyses found improved response rates and rates of remission for conventional rTMS and theta burst stimulation compared with sham TMS. Additionally, a head-to-head trial showed noninferiority of theta burst stimulation to conventional rTMS, with no difference in the incidence of adverse events. 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, while the effect of rTMS is less robust when it is given in combination with a stable dose of antidepressant medication. There is limited evidence to compare the effects of these treatments on cognition, although the adverse events of rTMS appear to be minimal. One meta-analyses have found that the effect of rTMS is smaller than the

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effect of ECT on TRD, given that rTMS does not require general anesthesia or induce seizures and some individuals may not elect ECT, the balance of incremental benefits and harms associated with rTMS may be reasonable compared with ECT. Two meta-analyses comparing MRI-based neuronavigated rTMS with scalp-based targeting methods for left DLPFC stimulation found no statistically significant difference in antidepressant efficacy between approaches. Four RCTs have evaluated accelerated TMS protocols for TRD: 2 sham-controlled trials of fMRI-guided SNT demonstrated high response and remission rates, while 1 sham-controlled trial without fMRI targeting also showed more significant benefits; a fourth trial demonstrated noninferiority of accelerated iTBS to standard deep TMS without requiring neuroimaging. It remains uncertain whether fMRI-guided targeting or MRI-based neuronavigation confers incremental benefit over standard coil placement, and long-term durability data beyond are limited across all accelerated protocols.

MIGRAINE HEADACHE

Clinical Context and Therapy Purpose
The purpose of rTMS is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with migraine headache pain.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with migraine headaches.

Interventions
The therapy being considered is rTMS.

Comparators
The following therapies are currently being used to treat migraine headache pain: pharmacotherapy (e.g., triptans, ibuprofen, combination analgesics).

Outcomes
The general outcomes of interest are reductions in symptoms and improvements in quality of life and functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

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Systematic Review

Saltychev et al (2022) conducted a systematic review and meta-analysis of 8 RCTs that compared rTMS to sham stimulation in patients with migraine.[25,] All RCTs used high-frequency rTMS to the left dorsolateral prefrontal cortex, and all studies except 1 included patients with chronic migraine. All studies except 1 had a low risk of bias and the risk of publication bias was nonsignificant. Results for the frequency of migraine days per month and the intensity of migraine pain both favored rTMS; however, the authors stated that the difference in migraine pain intensity was clinically insignificant. The analysis is summarized in Tables 4 and 5.

Table 4. Systematic Review & Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Saltychev et al (2022)[25],	2004-2021	8	Adults with migraine	339 (11 to 100)	RCTs	3 to 12 rTMS sessions over 3 days to 8 weeks

Table 5. Systematic Review & Meta-Analysis Results

Study	Migraine days per month	Migraine pain (scale of 0 to 100)
Saltychev et al (2022)[25,]		
N=339	N=339	N=257
Difference (95% CI)	-8.09 (-11.4 to -4.79)	-13.56 (-21.8 to -5.32)
I2	I2=87%	I2=86%

CI: confidence interval

Randomized Controlled Trial

A pivotal randomized, double-blind, multicenter, sham-controlled trial was performed with the Cerena TMS device to demonstrate the safety and effectiveness of a de novo application.[26,] Enrolled in the trial were 201 patients with a history of an aura preceding more than 30% of headaches of moderate or severe severity for approximately 90% of migraine attacks. Following a month-long baseline phase to establish the frequency and severity of the migraine, patients were randomized to a treatment phase consisting of 3 treatments or 3 months, whichever occurred first. Patients were instructed to treat their migraine headache during the aura phase and to record their pain severity (0 to 3), severity of associated migraine symptoms (photophobia, phonophobia, nausea), presence of vomiting, and use of rescue medications at the time of treatment and at 1, 2, 24, and 48 hours after treatment. The primary endpoint was the proportion of patients who were pain-free 2 hours after treatment. Of the 201 patients enrolled, 164 recorded at least 1 treatment and 113 recorded at least 1 treatment when there was pain. Post hoc analysis of these 113 patients showed a benefit of the device for the primary endpoint (37.74% pain free after 2 hours for Cerena vs. 16.67% for sham; p=.018) and for the proportion

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of subjects who were pain free after 24 hours (33.96% for Cerena vs. 10% for sham; p=.002). Active treatment was not inferior to sham for the proportion of subjects free of photophobia, suggesting that the device does not worsen photophobia. However, the device was not inferior to sham for the proportion of subjects free of nausea and phonophobia.

Section Summary: Migraine Headache
The available evidence on the use of TMS devices to treat migraine include a systematic review and a pivotal RCT. The systematic review found that rTMS reduced migraine pain and intensity compared to sham. The results of the pivotal trial were limited by the 46% dropout rate and post hoc analysis. According to the FDA labeling, the device has not been demonstrated as safe or effective when treating cluster headache, chronic migraine headache, or migraine headache during the aura phase. The device has not been demonstrated to be as effective in relieving the associated symptoms of migraine (photophobia, phonophobia, nausea).

OBSESSIVE-COMPULSIVE DISORDER

Clinical Context and Therapy Purpose
The purpose of rTMS is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with obsessive-compulsive disorder (OCD).

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with OCD.

OCD is characterized by the inability to suppress intrusive thoughts, impulses, images, and repetitive motor responses.

Interventions
The therapy being considered is rTMS.

The use of TMS for patients with OCD is based on the observation that OCD symptoms are associated with excessive activity in certain cortical areas. Transcranial magnetic stimulation is proposed as a treatment to modulate these brain areas.

Comparators
The following therapies are currently being used to treat OCD: pharmacotherapy, psychological, and behavioral therapy.

Outcomes
The general outcomes of interest are reductions in symptoms and improvements in quality of life and functional outcomes.

The Yale-Brown Obsessive Compulsive Scale (YBOCS) is a clinician-rated, 10-item scale commonly used to assess the severity of symptoms in OCD.[27,] Each item is rated from 0 (no symptoms) to 4 (extreme symptoms) (total range, 0 to 40), with separate subtotals for the severity of obsessions and compulsions.

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YBOCS scores of 0 to 13 correspond to 'mild symptoms' on the Clinical Global Impression of Severity (CGI-Severity=0 to 2), 14 to 25 with 'moderate symptoms' (CGI-Severity=3), 26 to 34 with 'moderate-severe symptoms' (CGI-Severity=4) and 35 to 40 with 'severe symptoms' (CGI-Severity=5 to 6).[28,] An improvement of ≥35% on the YBOCS is most predictive of treatment response.[29,]

Follow-up over months is of interest to monitor outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Systematic Reviews

Liang et al (2021) conducted a systematic review and meta-analysis of different TMS modalities for the treatment of OCD.[30,] Three of the 5 protocols assessed were significantly more efficacious than sham TMS, and all treatment strategies were similar to sham TMS regarding tolerability (Table 7). Transcranial magnetic stimulation was not more effective than sham TMS, but there was direct evidence from only 1 RCT for this comparison (Carmi et al, 2019, discussed in the next section).[31,] 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 rTMS strategies for OCD treatment.

Perera et al (2021) conducted a systematic review and meta-analysis of rTMS in the treatment of OCD.[32,] All RCTs in the analysis (n=26) had a low risk of bias. A random effects model was used to compare pre- and post-stimulation YBOCS scores, with effect sizes reported as Hedges' g. The analysis found that rTMS had a significant effect on YBOCS scores compared to sham (effect size, 0.64; 95% CI, 0.39 to 0.89; p<.0001). Raw mean difference in YBOCS score between treatments was 4.04 (95% CI, 2.54 to 5.54; p<.001). The effect size was still significant when 2 dominant trials were removed. Effect sizes with rTMS appeared to be significant until 4 weeks after treatment, and low- and high-frequency rTMS had similar efficacy to each other. The authors performed several subgroup analyses (cortical target, stimulation frequency, total pulses per session, total duration of treatment) but none of the effect sizes were significant between rTMS and sham.

Joseph et al (2025) conducted a systematic review and meta-analysis of 7 RCTs evaluating accelerated TMS (aTMS) protocols for OCD, defined as 2 or more sessions per day delivered over 1 to 3 weeks.[33,] Six studies (N=150; 77 active, 73 sham) were included in the quantitative

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analysis. aTMS significantly reduced OCD symptoms compared with sham (SMD, 0.63; 95% CI, 0.14 to 1.11; p=.01), with moderate heterogeneity across studies (I^2=51%; p=.07). Response rates were significantly higher with aTMS (OR, 4.28). Accelerated TMS also reduced depressive symptoms (SMD, 0.52), and this effect was sustained at follow-up (SMD, 0.74); however, the improvement in OCD and anxiety symptoms was not sustained at follow-up assessments ranging from 2 to 8 weeks. Adverse effects were more frequent in the aTMS group (OR, 5.16) but were described as mild, and dropout rates were similar between groups (OR, 0.74). GRADE assessment indicated moderate certainty for the primary outcome. The review was limited by small sample sizes across included trials, heterogeneity in patient populations regarding treatment resistance, varied stimulation protocols and cortical targets, and the small number of available RCTs.

Tseng et al (2025) published a network meta-analysis evaluating the efficacy and acceptability of non-invasive brain stimulation interventions for OCD.[34,] The analysis included 34 RCTs comprising 1,089 participants and 24 distinct stimulation methods, with searches conducted through January 27, 2023. The primary outcome was the change in overall OCD severity. Compared with sham controls, 3 interventions were associated with significant improvement in OCD severity: high-frequency rTMS over the bilateral dorsolateral prefrontal cortex (MD, -10.81; 95% CI, -20.80 to -0.82), high-frequency deep TMS over the bilateral dorsomedial prefrontal cortex/anterior cingulate cortex (MD, -9.74; 95% CI, -16.42 to -3.06), and low-frequency rTMS over the right dorsolateral prefrontal cortex (MD, -4.70; 95% CI, -8.84 to -0.57). The study was limited by heterogeneity across included participants and treatment contexts, including comorbidities, concomitant psychotropic medications, baseline OCD severity, timing of intervention, follow-up duration, and differing response definitions; incomplete assurance of blinding because of device limitations; and relatively short mean treatment and overall study durations, which may have underestimated delayed treatment effects.

Table 6. Systematic Review of Transcranial Magnetic Stimulation in Patients with Obsessive-Compulsive Disorder: Characteristics

Study	Dates	Trials Included	Participants	N (Range)	Design	Duration
Tseng et al (2025)[34,]	Up to January 2023	34	Mean age, 34.3 years; 49.1% women	1089	RCT, sham- or active-controlled	1 week to 8 weeks
Joseph et al (2025)	Up to 2024	7	NR	150 (77 active, 73 sham)	RCT, sham-controlled; accelerated protocols (≥2 sessions/day)	1 week to 3 weeks
Perera et al (2021)[32,]	Up to October 2020	26	Mean age, 33 years	781	RCT, sham-controlled	1 week to 6 weeks
Liang et al (2021)[30,]	Up to March 2020	22	Mean age, 34.1 years	698	RCT, sham- or active-controlled	1 week to 10 weeks

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OCD: obsessive-compulsive disorder; RCT: randomized controlled trial; SD: standard deviation.

Table 7. Systematic Review and Meta-Analysis: Results

Study	YBOCS Score	Dropouts
Tseng et al (2025)[34,]		
Total N	1089	
High-frequency rTMS applied over the bilateral dorsolateral prefrontal cortex	-10.81 (-20.80 to -0.82)	
High-frequency deep TMS applied over the dorsomedial prefrontal cortex/anterior cingulate cortex	-9.74 (-16.42 to -3.06)	
Low-frequency rTMS applied over the right dorsolateral prefrontal cortex	-4.70 (-8.84 to -0.57)	
Joseph et al (2025)[33,]	150	
Accelerated TMS vs. sham (SMD, 95% CI)	0.63 (0.14 to 1.11); I^2=51%; p=.01	
Response rate (OR, 95% CI)	4.28 (1.21 to 15.17); I^2=0%	
Perera et al (2021)[32,]		
Total N	781	781
	Mean difference (95% CI)	
Active rTMS	4.04 (2.54 to 5.54)	NR
	I2=62.06% ; p<.0001	
Liang et al (2021)[30,]		
	Mean Difference (95% CrI)	OR (95% CrI)

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Study	YBOCS Score	Dropouts
Low frequency rTMS applied over the dorsolateral prefrontal cortex	6.34 (2.12 to 10.42)	0.81 (0.08 to 8.17)
High-frequency rTMS applied over the dorsolateral prefrontal cortex	3.75 (1.04 to 6.81)	1.08 (0.37 to 3.19)
Low-frequency rTMS applied over the supplementary motor area	4.18 (0.83 to 7.62)	0.98 (0.37 to 2.67)
Low-frequency rTMS applied over the orbitofrontal cortex	4.43 (-2.57 to 11.31)	0.59 (0.06 to 5.68)
High-frequency rTMS applied over the anterior cingulate cortex/medial prefrontal cortex (deep TMS)	4.25 (-1.16 to 9.59)	1.62 (0.26 to 15.98)

CI: confidence interval; CrI: credible interval; NR: not reported; OR: odds ratio; rTMS: repetitive transcranial magnetic stimulation; SMD: standardized mean difference; YBOCS: Yale-Brown Obsessive-Compulsive Scale.

Randomized Controlled Trial

This section discusses in detail the sham-controlled RCT of deep TMS for OCD conducted by Carmi et al (2019).[31,] The trial was submitted to the FDA as part of the de novo classification request, to establish a reasonable assurance of safety and effectiveness of the device.[35,] Study characteristics and results are summarized in Tables 8 and 9, and limitations are shown in Tables 10 and 11. A total of 99 patients were randomized to active treatment or sham. The primary outcome was the difference between groups in the mean change from baseline to 6 weeks on the YBOCS. Secondary outcomes included the response rate (defined as a 30% or greater improvement from baseline on the YBOCS), the Clinical Global Impression of Improvement (CGI-I), the Clinical Global Impression of Severity (CGI-S), and the Sheehan Disability Scale, a patient-reported measure of disability and impairment. Results at 10 weeks were also reported as secondary outcomes.

The primary efficacy analysis used a modified ITT analysis (n=94), excluding 5 patients who were found to not meet eligibility criteria following randomization. There was a greater decrease from baseline 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). The FDA review provides data from the ITT analysis of the mean change in the YBOCS score (n=99). In the ITT data set, the YBOCS score decreased by -6.0 points (95% CI, -3.8 to -8.2) in the active group and by -4.1 points (95% CI, -1.9 to -6.2) in the sham group. Although the decreases were both statistically significant from baseline, the difference of 1.9 points between the treatment arms was not statistically significant (p=.0988). Results on the secondary outcomes were mixed. More patients in the active treatment group were considered improved based on the CGI-I and the CGI-S at 6 weeks, but there was no significant difference between groups on the Sheehan Disability Scale (Table 10).

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Table 8. Summary of Key Randomized Controlled Trial Characteristics - Transcranial Magnetic Stimulation for Patients with Obsessive-Compulsive Disorder

Study; Trial	Countries	Sites	Dates	Participants	Interventions		Duration of follow-up
Carmi et al (2019)[31],NCT02229903	U.S., Israel, Canada	11	2014-2017	N=99 adults ages 22 to 68 years, diagnosis of OCD as a primary disorder, receiving treatment in an outpatient setting, and having a YBOCS score >20; in maintenance treatment with a therapeutic dosage of a SRI for at least 2 months before randomization or, if they were not on an SRI, in maintenance treatment on CBT and have failed to respond adequately to at least 1 past trial of an SRI. Exclusions: primary axis I diagnosis other than OCD, severe neurological impairment, any condition associated with an increased risk of seizures.	Deep TMS 6-week treatment phase (consisting of 5 weeks of daily treatments 5 days a week and 4 treatments during the 6th week)	Sham	6 weeks (primary) 10 weeks (secondary)

CBT: cognitive behavioral therapy; OCD: obsessive-compulsive disorder; SRI: serotonin reuptake inhibitor; TMS: transcranial magnetic stimulation; YBOCS: Yale-Brown Obsessive-Compulsive Scale.

Table 9 Summary of Key Randomized Controlled Trial Results - Transcranial Magnetic Stimulation for Patients with Obsessive-Compulsive Disorder

Study	YBOCS (Primary Outcome)	YBOCS Response	CGI-I	CGI-S (modified)	Sheehan Disability Scale	Adverse events (all)	Dropouts
Carmi et al (2019)[31],NCT02229903	Mean change from	(>30% change from	Moderate to very				

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Study	YBOCS (Primary Outcome)	YBOCS Response	CGI-I	CGI-S (modified)	Sheehan Disability Scale	Adverse events (all)	Dropouts
	baseline at 6 weeks	baseline to 6 weeks)	much improved from baseline at 6 weeks				
N analyzed	94	94	94	94			
TMS	-6.0 points (95% CI, 4.0 to 8.1)	38.1% (16/42)	20/41 (49%)	25/41 (61%)	-3.8 points (95% CI, -1.5 to -6.1)	73%	6/48 (12.5%)
Sham	-3.3 points (95% CI, 1.2 to 5.3)	11.1% (5/45)	9/43 (21%)	14/43 (32.6 %)	-3.0 points (95% CI, -0.8 to -5.3)	69%	6/51 (12.0%)
Difference; P-value	2.8 points; p=.01 Effect size: 0.69	p=.003	p=.011	p=.022	NS (p-value not reported)	p=.639	NS (p-value not reported)

CGI-I: Clinical Global Impression of Improvement; CGI-S: Clinical Global Impression of Severity; CI: confidence interval; NS: non-significant; TMS: transcranial magnetic stimulation; YBOCS: Yale-Brown Obsessive-Compulsive Scale.

Table 10. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Carmi et al (2019)[31],NCT02229903					1,2. 6 weeks (primary)

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3.

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Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Carmi et al (2019)[31,]NCT02229903				6. Modified ITT analysis of 94/100 patients who were enrolled. The difference in the primary outcome was not statistically significant in the ITT data set (n=99)		

ITT: intention-to-treat.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Section Summary: Obsessive-Compulsive Disorder

The evidence on rTMS for OCD includes a number of small-to-moderate sized, sham-controlled, double-blind randomized trials and meta-analyses of these RCTs. A Multiple meta-analyses (ranging from 26 to 34 RCTs) have found a significant effect of rTMS on YBOCS scores compared to sham, with effect sizes in the small-to-moderate range, though the effect appears to persist only until approximately 4 weeks after treatment. Network meta-analyses have identified several stimulation approaches that may be effective, but deep TMS was not found to be more effective than sham based on limited direct evidence. A meta-analysis of 6 RCTs (N=150) found that accelerated TMS protocols (≥2 sessions/day over 1-3 weeks) significantly reduced OCD symptoms compared with sham (SMD, 0.63; p=.01) with higher response rates (OR, 4.28), though improvements were not sustained at 2-8 week follow-up assessments The RCT that was the basis of FDA clearance of deep TMS for treatment of OCD compared deep rTMS to sham in

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99 patients for 6 weeks, with an additional 4 weeks of follow-up as a secondary outcome. Using a modified ITT analysis (n=94), there was a larger mean decrease from baseline (improvement) on the 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 rTMS 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.

PSYCHIATRIC OR NEUROLOGIC DISORDERS OTHER THAN DEPRESSION, MIGRAINE, OR OBSESSIVE-COMPULSIVE DISORDER

Clinical Context and Therapy Purpose

The purpose of rTMS is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with psychiatric or neurologic disorders other than depression, migraine, or OCD.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with psychiatric or neurologic disorders other than depression, migraine, or OCD.

Interventions

The therapy being considered is rTMS.

Comparators

The following therapies are currently being used to treat psychiatric disorders other than depression or OCD: pharmacotherapy or psychological and behavioral therapy. The following therapies are currently being used to treat neurologic disorders other than migraine: pharmacotherapy and therapy as appropriate including either physical or occupational therapy.

Outcomes

The general outcomes of interest are reductions in symptoms and improvements in quality of life and functional outcomes.

Follow-up over months is of interest to monitor outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

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- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

PSYCHIATRIC DISORDERS OTHER THAN DEPRESSION OR OBSESSIVE-COMPULSIVE DISORDER

BIPOLAR DISORDER

Systematic Reviews

Konstantinou et al (2022) conducted a systematic review of 31 RCTs of rTMS for the treatment of bipolar disorder; meta-analysis was not performed.[36,] Most included studies were in the setting of bipolar depression (n=24). Only 8 studies had a low risk of bias. Overall, rTMS seems safe and well-tolerated but efficacy results are mixed and there is no consensus about the optimal rTMS regimen. The authors noted limitations of the available literature including heterogeneity among studies, differences in sham treatments, and small sample sizes. They also stated that adequately powered sham-controlled studies are needed to verify the efficacy of rTMS in patients with bipolar disorder.

Tee et al (2020) conducted a systematic review and meta-analysis of sham-controlled RCTs of rTMS for the treatment of bipolar disorder.[37,] Eight trials of rTMS in bipolar depression showed small but statistically significant improvements in depression scores compared to sham control (SMD, 0.302 ; p<.05). However, most studies had a high risk of bias, which could have exaggerated the treatment effects. The effect of rTMS was inconclusive in bipolar mania due to the high heterogeneity and limited number of controlled trials.

GENERALIZED ANXIETY DISORDER

Systematic Review

Qi et al (2024) included 7 RCTs (N=298) of rTMS for the treatment of generalized anxiety disorder in a systematic review and meta-analysis.[38,]Results showed that rTMS significantly reduced anxiety symptoms as measured by the Hamilton Anxiety Rating Scale (SMD, -1.17; 95% CI, -2.19 to -0.15). Response rates were higher in rTMS groups (RR, 0.61; 95% CI, 0.39 to 0.96), although remission did not reach statistical significance (RR, 0.73; 95% CI, 0.50 to 1.07). Headaches were more common in the intervention groups, but no differences in discontinuation were observed. The conclusions were limited by sample sizes and significant heterogeneity.

Cui et al (2019) included 21 studies (N=1481 patients) in a meta-analysis of rTMS plus drug therapy compared to drug therapy alone for the treatment of generalized anxiety disorder.[39,] Results of the analysis showed that rTMS improved anxiety symptoms as measured by the Hamilton Anxiety Scale (SMD, -0.68 ; 95% CI, -0.89 to -0.46). The conclusions that could be drawn from the body of evidence were limited by significant heterogeneity across studies, and the authors concluded that additional high-quality studies are needed to confirm the results.

PANIC DISORDER

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Systematic Review

A Cochrane review by Li et al (2014) identified 2 RCTs (N=40 patients) that compared low-frequency rTMS with sham rTMS over the right DLPFC.[40,] The larger of the 2 studies was a randomized, double-blind, sham-controlled trial by Mantovani et al (2013) who assessed 21 patients with panic disorder and comorbid major depression.[41,] The response was defined as a 40% or greater decrease on the Panic Disorder Severity Scale and a 50% or greater decrease in HAM-D scores. After 4 weeks of treatment, the response rate for panic was 50% with active rTMS and 8% with sham. The trial had a high-risk of attrition bias. The overall quality of evidence for the 2 trials was considered low, and the sample sizes were small, precluding certainty in the conclusions about the efficacy of rTMS for panic disorder.

POSTTRAUMATIC STRESS DISORDER

Systematic Review

Trevizol et al (2016) published a systematic review on the efficacy of low- and high-frequency rTMS for posttraumatic stress disorder.[42,] Five sham-controlled randomized trials (N=118 patients) were included. Most trials used stimulation of the right DLPFC, though some delivered rTMS to the left DLPFC or bilaterally. Three trials used high-frequency stimulation while 1 used low-frequency stimulation and another compared high- with low-frequency stimulation; the percent motor threshold ranged from 80% to 120%. Some trials provided rTMS in combination with a scripted narrative of the traumatic event, and different posttraumatic stress disorder scales were used. In a meta-analysis, active rTMS was found to be superior to sham (SMD, 0.74; 95% CI, 0.06 to 1.42), although heterogeneity across the trials was high.

Brown et al (2024) published a Cochrane systematic review of rTMS for posttraumatic stress disorder.[43,] The search was conducted through January 2023, and the authors identified 13 RCTs (N=577). Notably, 5 studies were conducted in the US, primarily enrolling white, male veterans. The authors found that rTMS probably makes little to no difference on posttraumatic stress disorder severity immediately following treatment (SMD, -0.14; 95% CI, -0.54 to 0.27; 3 studies, 99 participants; moderate-certainty evidence); however, there was significant heterogeneity amongst the studies.

SCHIZOPHRENIA

Systematic Reviews

Blyth et al (2025) included 126 studies (N=4122 participants) in a meta-analysis of rTMS safety in schizophrenia.[44,] Results showed that active rTMS was associated with higher rates of headache or scalp pain, dizziness or syncope, facial twitching, and nausea compared to sham ($p<.05$). The prevalence of seizure was low (1.39 per 1000) and not different from sham or from the general population. No increased risk of cognitive impairment, worsening psychosis, depression, or mania was observed.

He et al (2017) published a meta-analysis of the effects of 1-Hz (low frequency) and 10-Hz (high frequency) rTMS for auditory hallucinations and negative symptoms of schizophrenia, respectively.[45,] For 1-Hz rTMS, 13 studies were included. Compared with sham, the rTMS group showed greater improvement in auditory hallucinations (SMD, -0.29; 95% CI, -0.57 to -0.01).

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However, significant heterogeneity across the studies was found (p=.06). In the 7 studies using 10-Hz rTMS, the overall effect size for improvement in negative symptoms was -0.41 (95% CI, -1.16 to -0.35); again, there was significant heterogeneity across studies (p<.001). The review was further limited by the small number of articles included and by the lack of original data for some studies.

A Cochrane review by Dougall et al (2015) selected 41 studies (N=1473 participants).[46,] Based on very low-quality evidence, there was a significant benefit of low- and high-frequency temporoparietal TMS compared with sham for the global state (7 RCTs) and positive symptoms (5 RCTs). For prefrontal rTMS compared with sham, the evidence on global and cognitive state was of very low-quality and equivocal. Reviewers concluded that the evidence was insufficient to support or refute the use of TMS to treat symptoms of schizophrenia and, although some evidence suggested that temporoparietal TMS might improve certain symptoms (eg, auditory hallucinations, positive symptoms of schizophrenia), the results were not sufficiently robust to provide certainty.

Randomized Controlled Trials

Several additional small, single center RCTs of rTMS for the treatment of schizophrenia have been published since the systematic reviews described above (Tables 12 and 13).[47,48,49,50,51,52,53,] These studies were limited by their small sample sizes, very high loss to follow-up, and inadequate duration of follow-up (Tables 14 and 15). Due to these limitations, these studies do not provide sufficient evidence to draw conclusions about the effectiveness of the technology in patients with schizophrenia.

Table 12. Summary of Key Randomized Controlled Trial Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions1		Duration of follow-up
					Active	Comparator	
Ye et al (2024)[47,]	China	1	2016-2019	Inpatient male veterans diagnosed with schizophrenia per DSM-V criteria who were clinically stable on antipsychotic therapy ≥24 weeks (N=84 randomized)	Neuronavigation-guided high-frequency rTMS over left DLPFC: 10 Hz (1200 pulses per session) or 20 Hz (1600 pulses per session) administered 5 times a week (Monday to Friday) for 6 weeks (n=56	Sham rTMS (n=28)	24 weeks

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Study; Trial	Countries	Sites	Dates	Participants	Interventions1		Duration of follow-up
					total; 28 per group)		
Hua et al (2024)[48,]	China	1	2016-2021	Adults ages 18 to 60 diagnosed with schizophrenia per DSM-IV criteria and medication-resistant auditory verbal hallucinations who were clinically stable on antipsychotic therapy ≥2 weeks (N=66 randomized; 62 completed)	Imaging-navigated rTMS over left temporoparietal junction administered as 3 sessions per day for 14 consecutive days (n=32)	Sham rTMS (n=30)	6 weeks
Xiu et al (2024)[49,]	China	1	Not reported	Adults diagnosed with schizophrenia per DSM-IV criteria and persistent daily auditory verbal hallucinations despite ≥2 antipsychotics (N=120 randomized; 89 completed)	Neuronavigation-guided high-frequency rTMS over left DLPFC: 10 Hz (1,200 pulses per session) or 20 Hz (1,600 pulses per session) administered 5 times a week (Monday–Friday) for 8 weeks. (n=80; 40 in each group)	Sham rTMS (n=25)	32 weeks

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Study; Trial	Countries	Sites	Dates	Participants	Interventions1		Duration of follow-up
Zhu et al (2021)[53],	China	7	2017-2018	Inpatients ages 18 to 50 years with a diagnosis of schizophrenia per ICD-10 criteria who were right-handed and clinically stable for the past 3 months (N=64)	Intermittent theta burst stimulation over the cerebellum (3 pulses at 50 Hz repeated at a rate of 5 Hx for a total of 600 pulses administered 5 times a week (Monday to Friday) for 2 weeks (n=32)	Sham intermittent theta burst stimulation (n=32)	24 weeks
Guan et al (2020)[50],	China	1	Not reported	Male patients ages 20 to 60 years with a DSM-IV diagnosis of schizophrenia and>5-year duration of illness.	20 Hz stimulus on left DLPFC 40 sessions, administered 5 times a week (Monday to Friday) for 8 weeks (n=28)	Sham rTMS (n=28)	8 weeks
Kumar et al (2020)[51],	India	1	Not reported	Patients who were right-handed, clinically diagnosed as having schizophrenia as per ICD-10 criteria for at least 1 year; on stable doses of medicines (if receiving) for the last 4 weeks, but continued to have	Active rTMS: 20 sessions of high frequency rTMS per day (5 consecutive sessions per week for 4 weeks) at 20 Hz frequency (n=50)	Sham rTMS (n=50)	4 months

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Study; Trial	Countries	Sites	Dates	Participants	Interventions1		Duration of follow-up
				significant negative symptoms. Excluded patients who had received rTMS treatment in the past for a similar condition, comorbid ICD-10 Axis I diagnosis, or Axis II Personality Disorder or any other exclusion criteria common to every TMS protocol.			
Zhuo et al (2019)[52,]	China	1	2013-2014	Adults ages 20 to 60 years with a DSM-IV diagnosis of schizophrenia ; on a stable dose of antipsychotic medication for at least 1 month before study enrollment. Exclusions: DSM-IV-TR axis I disorder other than schizophrenia	Active rTMS: 20 treatment sessions on consecutive weekdays. 20 Hz rTMS applied to the left DLPFC (n=35)	Sham rTMS (n=35)	4 weeks

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Study; Trial	Countries	Sites	Dates	Participants	Interventions1		Duration of follow-up
				; history of epilepsy or seizure; significant or unstable neurologic disorder; cardiac pacemaker; previous brain injury or surgery; any metal clips, plates, or other metal items in the head; or substance dependency; or ECT within 3 months.			

DLPFC: dorsolateral prefrontal cortex; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition; ECT: electroconvulsive therapy; ICD-10: International Classification of Disease, 10th edition; rTMS: repetitive transcranial magnetic stimulation.

Table 13. Summary of Key Randomized Controlled Trial Results

Study	Main Results
Ye et al (2024)[47,]	During the 6-week treatment, 20 Hz rTMS, but not 10 Hz, produced greater gains in immediate memory compared with the sham group (p<.05). By 24 weeks, both 10 Hz and 20 Hz rTMS showed benefits on immediate memory and RBANS total score (p <.05).
Hua et al (2024)[48,]	At 2 weeks, rTMS significantly reduced AHRS scores compared with sham (MD, 5.96; p<.001), and this effect was sustained through week 6 (MD, 7.89; p<.001). Individuals in the rTMS group also reported significantly better response rates, PANSS scores, and HAMD scores at both the 2-week and 6-week assessments (p <.05).
Xiu et al (2024)[49,]	Significant differences were observed in favor of the 20Hz and 10Hz groups for immediate memory, delayed memory, language, and RBANS total score compared to the sham control at 6-month follow-up (p <.05).

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Study	Main Results
Zhu et al (2021)[53,]	At 2, 6, 12, and 24 weeks after the end of treatment, PANSS negative symptom scores were significantly lower in the rTMS group compared to the sham group (p<.05). The effect of treatment on positive symptoms and PANSS total scores was not significant.
Guan et al (2020)[50,]	At 2 weeks, 4 weeks, and 6 weeks, no significant differences in PANSS total score and sub scores between the sham and treatment groups. Immediate memory performance was higher in the rTMS group compared with the sham group at week 8 after covarying for education, age, and dose of drug. The improvement in immediate memory score was correlated with a decrease in the excitement factor score.
Kumar et al (2020)[51,]	Total SANS score was reduced significantly after the intervention in both the active (60.6 ± 11.75 to 43.9 ± 12.67 ; p<.01) and sham (61.5 ± 13.69 to 50.5 ± 14.11 ; p<.01) groups. Post-intervention scores were significantly lower among the subjects who received active rTMS as compared to those who received sham.
Zhuo et al (2019)[52,]	Significant decrease in negative symptoms but no significant improvement in cognition.

AHRS: Auditory Hallucination Rating Scale; HAMD: Hamilton Depression Rating Scale; MD: mean difference; PANSS: Positive and Negative Syndrome Scale; rTMS: repetitive transcranial magnetic stimulation; RBANS: Repeatable Battery for the Assessment of Neuropsychological Status; SANS: Scale for Assessing Negative Symptoms in Schizophrenia.

Table 14. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ye et al (2024)[47,]	4. Included inpatient men only				
Hua et al (2024)[48,]					1. 6 weeks not sufficient to show durability of effects
Xiu et al (2024)[49,]					
Zhu et al (2021)[53,]	4. Included inpatients only				

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Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Guan et al (2020)[50],	4. Included men only				1. 8 weeks not sufficient to show durability of effects
Kumar et al (2020)[51],					
Zhuo et al (2019)[52],					1. 4 weeks not sufficient to show durability of effects

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 15. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ye et al (2024)[47],				1. 25% of patients were lost to follow-up by 24 weeks	1. power calculation not reported	
Hua et al (2024)[48],				1. 4 discontinued in active vs 12 in sham by follow-up (26% dropout differential)		
Xiu et al (2024)[49],				1. 26% of patients were lost to follow-up by 32 weeks.	1. power calculation not reported	

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Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Zhu et al (2021)[53,]					1. power calculation not reported	
Guan et al (2020)[50,)]				1. 15/56 (26.8%) patients discontinued	1. power calculation not reported	
Kumar et al (2020)[51],				1. 33% attrition (32% active and 38% sham)		
Zhuo et al (2019)[52],				1. 10/70 discontinued (14.3%)	1. power calculation not reported	

The evidence limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
d Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

SUBSTANCE USE DISORDER AND CRAVING

Systematic Review

Jansen et al (2013) reported on results from a meta-analysis evaluating the effect of rTMS and transcranial direct current stimulation of the DLPFC on substance dependence (alcohol, nicotine, cocaine, marijuana) or food craving.[54,] Seventeen double-blind, sham-controlled trials that used high-frequency stimulation were analyzed. Thirteen studies stimulated the left DLPFC and 7 studies stimulated the right DLPFC or both sides. Twelve of the studies gave only 1 or 2 sessions. The standardized effect size was 0.476 (95% CI, 0.316 to 0.636), indicating a medium effect size for active stimulation over sham for a reduction in craving. However, the studies were small (range, 9 to 48 patients) and there was significant heterogeneity in selected studies. No significant differences were found in the effectiveness of rTMS versus transcranial direct current

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stimulation, the different substances, or the side of stimulation, although this analysis might have been biased by the number of studies for each condition.

Chang et al (2022) conducted a meta-analysis of 7 double-blind RCTs (N=462) that used rTMS to treat methamphetamine use disorder.[55,] All studies targeted the left DLPFC and the number of sessions ranged among studies from 5 to 20. Mean craving scores at baseline ranged from 22.63 to 57.68. A random effects model showed that clinical craving scores were significantly lower with rTMS than sham treatment (SMD, 0.983; 95% CI, 0.620 to 1.345; p≤.001; I2=67.814%). According to a subgroup analysis, intermittent theta burst stimulation had a greater effect than 10-Hz rTMS. The authors concluded that further trials with larger sample sizes are needed.

NEUROLOGIC DISORDERS OTHER THAN MIGRAINE

AMYOTROPHIC LATERAL SCLEROSIS OR MOTOR NEURON DISEASE

Systematic Review

A Cochrane review by Fang et al (2013) identified 3 RCTs with a total of 50 participants with amyotrophic lateral sclerosis that compared rTMS with sham TMS.[56,] All trials were considered of poor methodologic quality. Heterogeneity prevented pooling of results, and the high rate of attrition further increased the risk of bias. Reviewers concluded that evidence was insufficient to draw conclusions about the efficacy and safety of rTMS in the treatment of amyotrophic lateral sclerosis.

CHRONIC PAIN

Systematic Reviews

A Cochrane review by O'Connell et al (2018) evaluating noninvasive brain stimulation techniques was first published in 2010 and was updated in 2014[57], and 2018.[58,] The reviewers identified 42 RCTs (range, 4 to 70 participants) on TMS for chronic pain. Meta-analysis of 27 rTMS studies versus sham (N=655 participants) for pain intensity at short-term follow-up (0 to <1 week postintervention) demonstrated a small effect with heterogeneity (SMD, -0.22; 95% CI, -0.29 to -0.16, low-quality evidence). This equates to a 7% (95% CI, 5% to 9%) reduction in pain, or a 0.40 (95% CI, 0.53 to 0.32) point reduction on a 0 to 10 pain intensity scale, which did not meet the minimum clinically important difference threshold of 15% or greater. There is very low-quality evidence that single doses of high-frequency rTMS of the motor cortex may have short-term effects on chronic pain and quality of life, but multiple sources of bias exist that may have influenced the observed effects. We did not find evidence that low-frequency rTMS, rTMS applied to the DLPFC, and cranial electrotherapy stimulation are effective for reducing pain intensity in chronic pain.

Jiang et al (2022) conducted a systematic review and meta-analysis of 38 RCTs that assessed the analgesic effect of rTMS in 1338 patients with neuropathic pain.[59,] A single rTMS session was used in 13 studies and multiple sessions were used in the remaining 25 studies. The overall risk of bias in most studies was low or uncertain. According to a random effects analysis, rTMS was superior to sham therapy in reducing pain scores (effect size, -0.66; 95% CI, -0.87 to -0.46; p<.001; I2=78%). Beneficial effects of rTMS on pain were observed at 1 month (p<.001) and 2 months (p=.01). Low-frequency rTMS (≤1 Hz) did not effectively reduce pain compared to higher

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frequency stimulation. The analysis did not find an increased risk of adverse events with rTMS compared to sham therapy. The authors concluded that larger, well-designed trials are needed to determine the long-term effect of rTMS in this setting.

EPILEPSY

Systematic Reviews

A Cochrane review by Chen et al (2016) included 7 RCTs on low-frequency rTMS for epilepsy, 5 of which were completed studies with published data.[60,] The total number of participants was 230. All studies had active or placebo controls and 4 were double-blind. However, a meta-analysis could not be conducted due to heterogeneity in designs, interventions, and outcomes of the trials. Therefore, a qualitative synthesis was performed. For the outcome of seizure rate, 2 studies showed a significant reduction and 5 studies did not. Of the 4 studies evaluating the mean number of epileptic discharges, 3 studies showed a statistically significant reduction in discharges. Adverse events were uncommon and mild, involving headaches, dizziness, and tinnitus. There were no significant changes in medication use.

A more recent meta-analysis conducted by Mishra and colleagues (2020) included 7 RCTs that compared rTMS with sham or placebo controls in patients with epilepsy.[61,] Two of the included studies showed statistically significant reductions in the seizure rate from baseline, 3 trials failed to show any statistically significant difference in seizure frequency, and 2 had unclear results due to inadequate power. In a meta-regression, when adjusted for other potential variables such as the type of coil used, stimulation frequency, and the total duration of the active intervention, seizure frequency worsened by 2.00 ± 0.98 (p=.042) for each week of lengthening of the posttreatment follow-up period. These results suggested that rTMS exerted only a short-term effect. The reviewers concluded that although the procedure may be a therapeutic alternative for patients with drug-resistant epilepsy, further RCTs using standarized protocols and with adequate sample sizes and duration are still needed.

FIBROMYALGIA

Systematic Reviews

Ahmed et al (2025) included 43 RCTs (N=2120) in a network meta-analysis evaluating noninvasive brain stimulation for fibromyalgia.[62,] Low-frequency rTMS reduced pain intensity more than sham (SMD, -1.20; 95% CI -1.82 to -0.58), with high-frequency rTMS showing a smaller effect (SMD, -0.58; 95% CI -1.00 to -0.17). Low-frequency rTMS over the right dorsolateral prefrontal cortex (DLPFC) produced the most pronounced effects (SMD, -1.42; 95% CI -2.69 to -0.15) and maintained short-term improvements. High-frequency rTMS over the left primary motor cortex (M1) also reduced pain (SMD, -0.78; 95% CI -1.39 to -0.18). rTMS was well tolerated and achieved clinically meaningful pain reductions.

Su et al (2021) conducted a meta-analysis of 18 RCTs (N=643) with rTMS in patients with fibromyalgia.[63,] Reduction in disease influence according to the Fibromyalgia Impact Questionnaire showed a significant effect of rTMS (SMD, -0.7; 95% CI, -1.173 to -0.228). The effect of rTMS on disease influence, pain, depression, and anxiety lasted for at least 2 weeks after the last session. Older patients were most likely to experience reduced Fibromyalgia Impact

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Questionnaire scores. The authors concluded that larger RCTs are needed to confirm these findings.

Saltychev and Laimi (2017) published a meta-analysis of rTMS for the treatment of patients with fibromyalgia.[64,] The meta-analysis included 7 sham-controlled, double-blind trials with a low risk of bias. Trial sample sizes ranged from 18 to 54 patients. Five studies provided high-frequency stimulation to the left primary motor cortex, and the others were to the right or left DLPFC. The number of sessions ranged from 10 to 24, and follow-up ranged from immediately after treatment to 3 months posttreatment. In the pooled analysis, pain severity decreased after the last simulation by 1.2 points (95% CI, -1.7 to -0.8 points) on a 10-point numeric rating scale, while pain severity measured at 1 week to 1 month after the last simulation decreased by 0.7 points (95% CI, -1.0 to -0.3 points). Both were statistically significant, but not considered clinically significant, based on a minimal clinically important difference of 1.5 points.

PARKINSON DISEASE

Systematic Reviews

A meta-analysis by Chou et al (2015) included 20 sham-controlled randomized trials (N=470 patients) evaluating Parkinson disease.[65,] Sample sizes ranged from 8 to 102 patients. The total effect size of low- and high-frequency rTMS on Unified Parkinson's Disease Rating Scale part III score was 0.46, which is considered a small-to-medium effect size, and the mean change in the Unified Parkinson's Disease Rating Scale part III score (-6.42) was considered a clinically important difference. The greatest effect on motor symptoms was from high-frequency rTMS over the primary motor cortex (SMD , 0.77 ; p<.001) and low-frequency rTMS over other frontal regions (SMD , 0.50 ; p=.008). High-frequency rTMS at other frontal regions and low-frequency rTMS over the primary motor cortex did not have a statistically significant benefit. The largest trial included in the systematic review was an exploratory, multicenter, double-blind trial reported by Shirota et al (2013) who randomized 106 patients to 8 weeks of 1-Hz rTMS, 10-Hz rTMS, or sham stimulation over the supplementary motor area.[66,] At 9 weeks, all groups showed a similar amount of improvement.

Li et al (2022) conducted a meta-analysis of 32 sham-controlled RCTs of rTMS in patients with Parkinson disease and motor dysfunction (N=1048 patients).[67,] Motor dysfunction was assessed using the United Parkinson's Disease Rating Scale part III score. Overall, rTMS had a significant effect on motor symptoms compared to sham (SMD, 0.64; 95% CI, 0.47 to 0.80; p<.0001; I2=64%). High-frequency rTMS to the primary motor cortex was the most effective intervention. Significant benefit of rTMS was also demonstrated for akinesia, rigidity, and tremor.

STROKE RECOVERY

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Systematic Reviews

A number of RCTs and systematic reviews have evaluated rTMS for recovery from stroke. For example, a Cochrane review by Hao et al (2013) included 19 RCTs (N=588 participants) evaluating the effect of low- and high-frequency TMS for improving function after stroke.[68,] The 2 largest trials (n=183 patients) showed that rTMS was not associated with a significant improvement in Barthel Index scores. Four trials (n=73) found no significant effect on motor function. Subgroup analyses for different stimulation frequencies or durations of illness also did not show a significant benefit of rTMS compared with sham rTMS or no treatment. Reviewers concluded that current evidence did not support the routine use of rTMS for the treatment of stroke.

A meta-analysis by Le et al (2014) assessed the effect of rTMS on the recovery of hand function and excitability of the motor cortex after stroke.[69,] Eight RCTs (N=273 participants) were selected. The quality of the trials was rated moderate to high, although the size of the studies was small. There was variability in the time since stroke (5 days to 10 years), in the frequency of rTMS applied (1 to 25 Hz for 1 second to 25 min/d), and the stimulation sites (primary motor cortex or premotor cortex of the unaffected hemisphere). Meta-analysis found a positive effect on finger motor ability (4 studies; n=79 patients; SMD, 0.58) and hand function (3 studies; n=74 patients; SMD, -0.82), but no significant change in motor evoked potentials (n=43) or motor threshold (n=62).

A meta-analysis by Li et al (2015) included 4 RCTs on low-frequency rTMS over the right parstriangularis for patients (N=137) with aphasia after stroke.[70,] All studies used double-blinding, but therapists were not blinded. Every trial used a different outcome measure, and sample sizes were small (range, 12 to 40 patients). Meta-analysis showed a medium effect size for naming (p=.004), a trend for a benefit on repetition (p=.08), and no significant benefit for comprehension (p=.18). Additional study in a larger number of patients would be needed to determine with greater certainty the effect of this treatment on aphasia after stroke.

Qiao et al (2022) performed a meta-analysis of RCTs that assessed the effect of rTMS in 433 patients with post-stroke dysphagia.[71,] Twelve trials that used dysphagia severity rating scales (Dysphagia Grade and Penetration Aspiration Scale) were included. The specific controls used in each study were not specified. Study characteristics included duration of treatment of 1 to 10 days, stimulation frequency of 1 to 10 Hz, and duration of stimulation of 5 to 20 minutes. The analysis favored rTMS (SMD, -0.67; 95% CI, -0.88 to -0.45; p<.001; I2=42%). Subgroup analyses identified treatment duration >5 days and rTMS during the subacute phase after stroke as potential situations with greater clinical benefit, but there was no difference in efficacy according to stimulation frequency, location, or duration of each stimulation. The authors noted that publication bias was present and there may be limited clinical applicability of the dysphagia rating scales.

Zhang et al (2017) published a systematic review and meta-analysis evaluating the effects of rTMS on upper-limb motor function after stroke.[72,] A search through October 2016 yielded 34 RCTs with a total of 904 participants (range, 6 to 108 participants). Pooled estimates found improvement with rTMS for both short-term (SMD, 0.43; p<.001) and long-term (SMD, 0.49; p<.001) manual dexterity. Of the 28 studies reporting on adverse events, 25 studies noted none.

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Mild adverse events, such as headache and increased anxiety, were reported in 3 studies. The review was limited by variation in TMS protocols across studies.

Graef et al (2016) reported a systematic review of rTMS combined with upper-limb training for improving function after stroke.[73,] Included were 11 sham-controlled randomized trials with 199 patients that evaluated upper-limb motor and functional status and spasticity; 8 RCTs with sufficient data were included in the meta-analysis. These studies were considered to have a low-to-moderate risk of bias. In the overall analysis, there was no benefit of rTMS on upper-limb function or spasticity (SMD, 0.03; 95% CI, -0.25 to 0.32).

Zhang et al (2024) conducted a systematic review and meta-analysis of 37 RCTs (N=1887) assessed as having a low risk of bias evaluating rTMS for motor recovery after stroke.[74,]Pooled results showed significant improvements in upper-limb motor function following rTMS at last follow-up compared to control on the Fugl-Meyer Assessment (SMD 5.2; 95% CI, 0.5 to 10.0; p<.001; I^2=98%), with larger effects in acute/subacute stroke and in patients with more severe baseline deficits. Among secondary measures, only the modified Rankin Scale improved (SMD = -0.5; 95% CI, -0.9 to -0.1; p=.013; I2 = 83%); Action Research Arm Test (ARAT), Box and Block Test (BBT), and Modified Ashworth Scale (MAS) showed no between-group differences. Substantial heterogeneity was present for all estimates, and trials varied widely in terms of rTMS target site, intensity, number of sessions, and pulses per day.

Section Summary: Psychiatric or Neurologic Disorders Other Than Depression, Migraine, or Obsessive-Compulsive Disorder
For individuals who have psychiatric disorders other than depression or OCD (eg, panic disorder, generalized anxiety disorder, posttraumatic stress disorder, schizophrenia, substance use disorder and craving) who receive rTMS, the evidence includes numerous small RCTs and meta-analyses of these studies. 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. A number of sham-controlled randomized trials and meta-analyses of these have found a medium effect size of rTMS for the reduction of substance dependence or food craving. Most studies examined acute craving after 1 or 2 rTMS sessions, and there is limited evidence on the longer-term efficacy of this treatment approach. There are no large, high-quality trials for any of these conditions demonstrating efficacy or the durability of any treatment effects.

For individuals who have neurological disorders other than migraine (eg, amyotrophic lateral sclerosis, chronic pain, epilepsy, fibromyalgia, Parkinson disease, and stroke) who receive rTMS, the evidence includes numerous small RCTs and meta-analyses of these randomized trials. 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.

SUPPLEMENTAL INFORMATION
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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Clinical Input From Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input
In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2014. Reviewers considered repetitive transcranial magnetic stimulation (rTMS) to be medically necessary for treatment-resistant depression. Input agreed with the proposed criteria for treatment of treatment-resistant depression with rTMS, as included in the policy statement.

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.[75,] 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.[76,] 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."

International Headache Society
In 2025, the International Headache Society (IHS) published evidence-based guidelines on the use of non-invasive neuromodulation devices for the acute and preventive treatment of migraine.[77,] The guideline was developed by a working group using GRADE methodology and a systematic review of 6 databases from 1946 through April 2025; 15 studies met inclusion criteria

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for the evidence-based recommendations. Evidence quality ranged from very low to moderate. For acute migraine treatment, the panel issued weak (conditional) recommendations in favor of SAVI Dual, Cefaly, Relivion, and Nerivio. For preventive migraine treatment, weak recommendations in favor of gammaCore Sapphire, Cefaly, and Nerivio were issued. Other cleared devices received no recommendation or had no eligible studies for GRADE assessment. The primary limitations across studies were imprecision due to small sample sizes and methodological concerns. The panel concluded that non-invasive neuromodulation devices offer promising alternatives to drug treatment for migraine, are generally safe and well tolerated, and are devoid of drug interactions, but that additional higher-quality studies are needed to better define their role in clinical practice.

International Neuromodulation Society/North American Neuromodulation Society

In 2020, an expert consensus panel from the International Neuromodulation Society-North American Neuromodulation Society performed a literature review and published recommendations for transcranial magnetic stimulation in the treatment of pain and headache.[78,] For neuropathic pain, the panel recommended transcranial magnetic stimulation to the primary motor cortex (high level evidence) or the left dorsolateral prefrontal cortex (F3 location) (at least moderate level evidence). For postoperative pain, the panel recommended that transcranial magnetic stimulation to the F3 location be only selectively offered due to at least moderate certainty that the net benefit is small. For primary headache, the panel only based 2 recommendations on moderate certainty evidence: single transcranial magnetic stimulation for acute migraine and high-frequency rTMS to the primary motor cortex for migraine prevention. For posttraumatic brain injury, high level evidence supported a recommendation for high-frequency transcranial magnetic stimulation to the primary motor cortex or the F3 location.

National Network of Depression Centers/Clinical TMS Society/International Federation of Clinical Neurophysiology

In 2025, the National Network of Depression Centers (NNDC) Neuromodulation Task Group published an updated consensus review on TMS for the treatment of depression, endorsed by the Clinical TMS Society and the International Federation of Clinical Neurophysiology.[79,·] The panel equally recommended iTBS and standard high-frequency rTMS as "appropriate initial antidepressant treatment protocols," based on non-inferiority data. The Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol was noted as FDA-cleared and promising, but the consensus stated that "additional studies are needed" for independent replication and long-term durability assessment. Regarding maintenance TMS, the consensus characterized the evidence as "promising, although the frequency of maintenance treatments needed to sustain benefit is unclear," and called for "larger scale randomized controlled trials." For bipolar depression, the panel found a smaller magnitude of effect with concern for treatment-emergent mania. For other mood disorders, including PTSD, depression secondary to traumatic brain injury, and depression in the context of substance use disorders, the evidence was described as "mixed and limited, with no definitive conclusions or consensus recommendations at this juncture." The consensus also updated the contraindication threshold for ferromagnetic material near the TMS coil from 30 cm to 10 cm based on updated safety data. The panel recommended that patients receive the full treatment course of 30 to 36 sessions and that rTMS be considered earlier in antidepressant treatment algorithms, given evidence that rTMS augmentation may be superior to switching pharmacologic agents in treatment-resistant depression.

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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.[80,]

In 2014, the NICE provided guidance on the use of rTMS for treating and preventing migraine.[81,] 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.

In 2020, the NICE stated that rTMS has not demonstrated any major safety concerns for management of obsessive-compulsive disorder or auditory hallucinations, but evidence for both uses is lacking; therefore, NICE recommends that rTMS be used in patients with these conditions only in the context of research.[82,83,]

Veteran's Affairs/Department of Defense

The 2022 Veteran's Affairs/Department of Defense (VA/DoD) guideline for management of major depressive disorder recommends offering rTMS to patients who have experienced partial response or no response to an adequate trial of 2 or more pharmacologic treatments (strength of recommendation: weak).[84,] Recommended options for the second treatment attempt after the initial therapy tried include switching to another antidepressant or adding augmentation therapy with a second-generation antipsychotic. The recommendation for rTMS was graded as weak due to limitations of the available literature including small study effects, high rates of discontinuation, lack of allocation concealment, and the practical limitations of the need for daily treatment and lack of widespread access to facilities that offer this therapy. The guideline also concluded that there is limited evidence to recommend for or against theta-burst stimulation for treatment of depression.

The 2023 VA/DoD guideline for management of bipolar disorder states "for individuals with bipolar disorder who have demonstrated partial or no response to pharmacologic treatment for depressive symptoms, we suggest offering repetitive transcranial magnetic stimulation [rTMS] as an adjunctive treatment."[85,] However, the recommendation was rated as "weak" and the confidence in the evidence was very low. For the management of PTSD, the 2023 guideline found insufficient evidence for or against rTMS.[86,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in Table 16.

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Table 16. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT02910024	Theta-Burst-Stimulation in Early Rehabilitation of Stroke (TheSiReS)	150	Sep 2022
NCT03556722	Effectiveness and Tolerability of Repetitive Transcranial Magnetic Stimulation For Preventive Treatment Of Episodic Migraine: A Single Centre, Randomised, Double-Blind, Sham-Controlled Phase 2 Trial	76	Apr 2022
NCT06524505	Efficacy, Tolerability, and Cognitive Effects of Deep Transcranial Magnetic Stimulation for Bipolar Depression: a Double-blind, Randomized Controlled Trial	100	Oct 2024
Ongoing			
NCT06545474	Repetitive Transcranial Magnetic Stimulation (rTMS) as an Early Intervention in Major Depression (MD) Compared to Antidepressant Selective Serotonin Reuptake Inhibitor (SSRI) Medication (Early-TMS)	106	Dec 2026
NCT06370988	Theta-Burst Stimulation for Bipolar Depression	124	May 2029
NCT05389670	Theta-burst Repetitive Transcranial Magnetic Stimulation (TBS) of the Right Inferior Frontal Gyrus for Treatment of Nicotine Dependence	60	Apr 2026
NCT05331937	Transcranial Magnetic Stimulation (TMS) for Patients With Exposure Therapy-resistant Obsessive-compulsive Disorder (OCD): TETRO - a Multicenter Randomized Controlled Trial	250	Sep 2027
NCT05100888	Theta-burst rTMS in Schizophrenia to Ameliorate Negative and Cognitive Symptoms: a Double-blind, Randomized Clinical Trial	90	April 2026
NCT06783361	Accelerated Transcranial Magnetic Stimulation in Treatment-Resistant Depressed Patients	60	Aug 2025

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NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT05849402	Accelerated Intermittent Theta-Burst Stimulation (aiTBS) in Treatment-Resistant Depression of Bipolar II Disorder	60	July 2026
NCT05680727	Individualized Functional Connectivity Targeting in aiTBS for Depression (AINT)	40	Mar 2027
NCT04318977	rTMS Add on Value for Amelioration of Negative Symptoms of Schizophrenia (RADOVAN)	62	Dec 2025

NCT: national clinical trial.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

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

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent deliver and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment
0891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

REVISIONS	
12-07-2012	Policy added to the bcbsks.com web site.
05-07-2013	Updated Description section.
	Updated Rationale section.
	Updated Reference section.
10-15-2014	Updated Description section.
	In Policy section: Removed the following, "Transcranial magnetic stimulation of the brain is considered investigational as a treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches." And added:

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REVISIONS	
	A. 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 (1-3) have been met: 1. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms; AND 2. Any one of the following (a, b, c, or d): a. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials; OR b. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; OR c. History of response to rTMS in a previous depressive episode (at least 3 months since the prior episode); OR d. Is a candidate for electroconvulsive therapy (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 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. B. rTMS for major depressive disorder that does not meet the criteria listed above is considered experimental / investigational. C. Continued treatment with rTMS of the brain as maintenance therapy is considered experimental / investigational.
	Added Policy Guideline section.
	In Coding section: • Added ICD-9 diagnoses: 296.23, 296.33 • Added ICD-10 diagnoses: F32.2, F33.2
	Updated Rationale section.
	Updated References section.
03-18-2015	Updated Description section.
	In Policy section: ▪ Added Item D: " Transcranial magnetic stimulation of the brain is considered experimental / investigational as a treatment of all other psychiatric/neurologic disorders, including but not limited to bipolar disorder, schizophrenia, obsessive-compulsive disorder, or migraine headaches."
	Updated Rationale section.
	Updated References section.
02-17-2016	Updated Description section.
	Updated Rationale section.
	Updated References section.
08-15-2017	
	Updated Description section.
	Updated Rationale section.
	Updated References section.
11-07-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.

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REVISIONS	
	Updated References section.
05-22-2020	Updated Description section
	In Policy section: Update Policy Guidelines ▪ Added Items 2 and 3 to read "2. The physician is responsible for the initial mapping (once per course or delivery) and the management of the treatment. The physician is also responsible for the re-determinations. 3. A trained technician may perform the subsequent delivery of treatment." ▪ In Item 5 a removed "An attendant trained" and "as well as the use of the equipment" to read "A trained technician in administration of the treatments, and in basic cardiac life support, the management of complications such as seizures, must be present at all times;"
	Updated Rationale section
	Updated References
04-16-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
12-18-2021	Updated Title to: Transcranial Magnetic Stimulation (TMS) as a Treatment of Depression and Other Psychiatric/Neurologic Disorders
	Updated Description Section
	Updated Policy Section: ▪ Section A to read: Repetitive transcranial magnetic stimulation (rTMS) 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 (1-3) have been met:
	Updated Policy Guidelines ▪ Added lines 4, 5, 7, 9
	Updated Rationale Section
	Updated Coding section: ▪ Added ICD-10 Codes: F32.2, F32.3, F32.4, F32.5, F33.3, F33.8
	Updated References Section
12-29-2022	Updated Description Section
	Updated Policy Section ▪ Section A2a Changed to read: "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: i. The trial length was at least 6 weeks at generally accepted doses; AND ii. Individual was ≥80% adherent to the agent during the trial." ▪ Section A2b Removed: "as evidenced by 4 trials of psychopharmacologic agents with" and added "due to"
	Updated Rationale Section

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	Updated References Section
11-17-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section ▪ Removed ICD-10 Codes
	Updated References Section
07-01-2024	Updated Coding Section ▪ Added codes 0889T, 0890T, 0891T and 0892T (eff. 07-01-2024)
12-03-2024	Updated Description Section
	Updated Rationale Section
	Updated References Section
02-25-2025	Updated Policy Section ▪ Removed A3: "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."
12-09-2025	Updated Description Section
	Updated Rationale Section
	Updated Reference Section
07-14-2026	Updated Description Section
	Updated Policy Guidelines Section ▪ Changed Statement A from 18 to 15 ▪ Added to Statement I another is the Brainsway SWIFT protocol, consisting of 5 daily sessions for 6 days using standard H1-coil positioning without neuroimaging (K251449, September 2025). It is not established whether fMRI-guided targeting confers incremental benefit over standard coil placement in accelerated protocols, and long-term durability data are limited.
	Updated Rationale Section
	Updated Reference Section
10-15-2026	Updated Description Section
	Updated Rationale Section
	Updated Reference Section

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