



**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria

Transcranial Magnetic Stimulation (TMS) for Treatment-Resistant Depression

- Medical Diagnoses
- Migraine Headaches
- Treatment Resistant Depression

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Transcranial Magnetic Stimulation (TMS) (L37088)
Local Coverage Article (LCA)	Billing and Coding: Transcranial Magnetic Stimulation (TMS) (A57693)

For Non-Medicare Members

Service	Criteria Used
TMS	
Behavioral Health (treatment resistant depression)	<p>Effective until August 1, 2024 MCG* B-KP-801-T For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p> <p>Effective August 1, 2024 MCG* B-KP-801-T 08012024 For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.</p>
Other diagnoses	Requires Medical Director Review

***MCG Care Guidelines are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Repetitive Transcranial Magnetic Stimulation (rTMS)

Major depressive disorder is a common health condition, and is associated with substantial morbidity, mortality and health care costs. No single approach is uniformly effective at treating depression. Antidepressant treatment with SSRIs is currently a common first step. Approximately, two-thirds of patients respond to an initial course of antidepressants (O'Reardon et al., 2000). One alternative for non-responders is to switch to a different antidepressant, in the same or another class of medications. Findings from a recent RCT indicate that approximately 1 in 4 individuals who failed an initial course of SSRIs respond to a second one (Rush et al., 2006). Adding psychotherapy is another option for non-responders.

Interest in alternative treatment options, such as transcranial magnetic stimulation (TMS), has grown in recent years. TMS is a non-invasive method of modulating the brain's electrical environment by using magnetic fields. The technique involves applying alternating electrical currents through an insulated coil on the scalp which, ultimately, produces an electrical field in the brain, which in turn induces depolarization of nerve cells and results in the stimulation or disruption of brain activity. Changes in brain activity with TMS can be detected through various imaging techniques (PET, SPECT, or MRI). TMS can be delivered in either individual or repetitive pulses (the latter known as rTMS). Most studies of TMS for depression use repetitive pulses and target the left dorsal lateral prefrontal cortex (DLPFC). Reported side-effects of TMS are generally mild including headache, local discomfort, and transient change in auditory threshold, which can be prevented by the use of earplugs. Instances of mania and epileptic seizure, however, have been known to occur (Fitzgerald and Daskalakis 2008; George 2010; Shelton, Osuntokun et al. 2010; Slotema, Blom et al. 2010).

Several TMS devices, including the NeuroStar TMS system (Neuronetics, Atlanta, GA) and the Brainsway Deep TMS system (Brainsway Ltd., Jerusalem, Israel), have received 510(k) clearances by the United States Food and Drug Administration (FDA). The devices are indicated for the treatment of major depressive disorder (MDD) in adult patients who have failed one prior antidepressant medication at or above the minimal effective dose and duration. The medical technology and assessment committee (MTAC) previously reviewed TMS technology in 2009, and subsequently in 2011. In each case, the evidence failed to satisfy MTAC criteria due to inappropriate comparators and lack of established long-term efficacy.

Deep Transcranial Magnetic Stimulation (dTMS).

dTMS is a further development of the conventional rTMS. It uses a novel electromagnetic coil "the Hesel-coil or H-coil" which has a unique configuration designed to activate the brain tissue at a greater depth. The H-coil, comes in different variations and features, and unlike the conventional 8-figure coil, the H-coils that deliver the magnetic pulses are placed in a hood that is fitted to the head of the patient during treatment. The H-coils generate magnetic pulses that can penetrate 3-6 cm beneath the skull to stimulate deeper regions and neural pathways of the brain and produce antidepressant effects of greater magnitude compared to conventional rTMS. Each dTMS session includes a series of 2-second stimulations with a frequency of 18-20 Hz followed by a 20-second pause. One treatment session is thus equivalent to 40-55 stimulations, with a total of approximately 1700-2000 magnetic pulses delivered in 15-20 minutes. The acute treatment is administered 5 days a week for 4-5 weeks and is usually followed by maintenance phase in which treatment is delivered less often for up to 12 weeks (Roth 2007, Levkovitz 2015, Kedzior 2016, Nordenskjold 2016).

Reported side effects include scalp discomfort, transient headache and dizziness, insomnia, perceiving an odd smell, numbness in the right cervical zone, and very rarely convulsions. The TMS machine produces loud snapping noises during stimulation and the patients are given earplugs for protection against hearing damage. However, some patients may still complain of hearing problems immediately following treatment (Bewernick 2015, Nordenskjold 2016).

An absolute contraindication to the use of any TMS is the presence of metallic or ferromagnetic objects in the head or eye, cochlear implants, implanted pacemakers, or other implants. Relative contraindications include history of previous epilepsy, skull trauma, cerebral damage of any etiology, severe headache or migraine, hearing loss, substance abuse, pregnancy, severe or recent heart disease, and systemic disease (Nordenskjold 2016, Valero Cabre 2017).

In 2013, the Brainsway Deep TMS system (Brainsway Ltd., (Har Hotzvim, Jerusalem, Israel), have received 510(k) clearances by the United States Food and Drug Administration (FDA) for the treatment of depressive episodes in adult patients suffering from Major Depressive Disorder who failed to achieve satisfactory improvement from previous anti-depressant medication treatment in the current episode. The Brainsway dTMS system is composed of an electromagnetic coil (H1 Coil), TMS neurostimulator, cooling system, a positioning device, and a cart.

Medical Technology Assessment Committee (MTAC)

Repetitive transcranial magnetic stimulation (rTMS)

06/01/2009: MTAC REVIEW

Evidence Conclusion: Active rTMS vs. sham treatment for treatment-resistant depression

Efficacy: There is insufficient evidence on the long-term efficacy of rTMS for treatment-resistant depression. In the RCTs, patients were generally evaluated at the end of the treatment period, 4 weeks or less. A pooled analysis of the 4 studies that followed patients for an additional 1-2 weeks also found a significantly higher response rate with rTMS vs. sham treatment. There is sufficient evidence from a meta-analysis of 21 RCTs (Lam et al., 2008) that there is a higher short-term clinical response rate with rTMS compared to sham treatment (NNT=6). **Safety:** In the Lam meta-analysis, there was a low rate of withdrawals due to adverse effects overall, 2% of patients in the active rTMS group and 1.5% in the sham group. Janicak et al. (2008), in a study funded by Neuronetics, compiled safety data from one sham-controlled RCT and two unpublished open-label studies and found few treatment-related adverse effects. No deaths or seizures were reported among the 218 patients receiving active treatment. A total of 41 serious adverse events were reported. 36 of the 41 were assessed by study investigators as unrelated to the study device. The 5 related events included 3 related to a manufacturing defect in a component of the study device, 1 was left-sided facial numbness and the fifth, deemed probably related, was not specified.

rTMS vs. other established treatment for treatment-resistant depression: There is insufficient evidence to draw conclusions about the safety and efficacy of rTMS for treatment-resistant depression compared to electroconvulsive therapy. One RCT comparing rTMS to ECT in this population was identified (Rosa et al., 2006). The study did not find a significant difference in the rate of clinical remission with rTMS compared to ECT. There were a relatively small number of patients enrolled, a relatively high drop-out rate and no analysis of statistical power, so conclusions cannot be made about equivalence of the treatments. There is insufficient evidence to draw conclusions about the safety and efficacy of rTMS for treatment-resistant depression compared to additional trials of antidepressants. No trials were identified comparing monotherapy with rTMS or antidepressants in this population. One RCT compared the combination of rTMS and escitalopram to escitalopram (plus sham rTMS) (Bretlau et al., 2008). The study, which included patients who failed at least one previous trial of antidepressants, used the difference in depression scores as the primary outcome, rather than the more clinically significant outcomes, clinical response or remission. With an appropriate statistical analysis, adjusting for multiple comparisons, there was a significant benefit of the combined active treatment group at the end of the three-week rTMS period, but no difference after an additional 9 weeks of medication treatment.

Articles: Active rTMS vs. sham treatment for treatment-resistant depression

The Pubmed searched yielded three meta-analyses of RCTs comparing rTMS for major depression to sham treatment. Only one of the three meta-analyses (Lam et al., 2008) focused on treatment-resistant depression, the FDA-approved indication and was critically appraised. No major sham-controlled RCTs were published after the meta-analysis literature search date (May 15, 2008). The search of the Cochrane database yielded a systematic review of rTMS for depression, but this review had not been updated since 2001 and was therefore excluded. A study that compiled safety data from several trials (Janicak et al., 2008) was reviewed, but an evidence table was not created. rTMS vs. other established treatment for treatment-resistant depression. One RCT comparing rTMS to ECT for patients with treatment-resistant depression (Rosa et al., 2006) was identified and critically appraised. Another RCT comparing rTMS and ECT had as its entry requirement, referral for ECT. The investigators did not specify that patients needed to have failed at least one treatment, so this study was excluded from further review. One RCT comparing rTMS to antidepressants for medication-resistant depression (Bretlau et al., 2008) was identified and critically appraised. Two other RCTs that evaluated the combination of rTMS and antidepressants as first-line treatment were excluded. The references for the studies that were reviewed are as follows: Bretlau LG, Lunde M, Unden M et al. Repetitive transcranial magnetic stimulation (rTMS) in combination with escitalopram in patients with treatment-resistant major depression. *Pharmacopsychiatry* 2008; 41: 41-47. See [Evidence Table 1](#). Janicak PG, O'Rearson JP, Sampson SM et al. Transcranial magnetic stimulation in the treatment of major depressive disorder: A comprehensive summary of safety experience from acute exposure, extended exposure and during reintroduction treatment. *J Clin Psychiat* 2008; 69: 222-232. Lam RW, Chan P, Wilkins-Ho M et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: A systematic review and meta-analysis. *Can J Psychiatr* 2008; 53: 621-631. See [Evidence Table 2](#). Rosa MA, Gattaz WF, Pascual-Leone A et al. Comparison of repetitive transcranial magnetic stimulation and electroconvulsive therapy in unipolar non-psychotic refractory depression: a randomized, single-blind study. *Int J Neuropsychopharm* 2006; 9: 667-676. See [Evidence Table 1](#).

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of treatment-resistant major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

04/18/2011: MTAC REVIEW

Repetitive Transcranial Magnetic Stimulation (rTMS)

Evidence Conclusion: *rTMS vs. sham rTMS:* A recent RCT evaluated the safety and efficacy of daily left prefrontal cortex rTMS compared to sham rTMS for the treatment of antidepressant medication resistant depression in 190 patients with unipolar depression. The primary outcome was remission defined as a Hamilton Scale for Depression (HAM-D) score ≤ 3 or 2 consecutive HAM-D scores less than 10. Thirteen patients in the active rTMS group and five patients in the sham rTMS group experienced remission [Odds ratio 4.18, 95% CI (1.32-13.24), NNT=12]. There was no significant difference in adverse events by treatment arm. Results from this trial suggest that rTMS is more effective than placebo at treating medication resistant depression; however, this trial does not address the duration of the effect (George 2010). *rTMS vs. venlafaxine ER* the efficacy of rTMS over the right prefrontal dorsolateral cortex versus venlafaxine ER for the treatment of resistant depression was assessed in a recent RCT that followed 60 patients for 4-weeks. The primary outcome measure was change in Montgomery-Åsberg Depression Rating Scale (MADRS) score. Clinical response (more than a 50% reduction of the MADRS score) and remission (MADRS score ≤ 10 points) were also evaluated. There was no significant difference in mean change in MADRS score, clinical response, or remission rates between the two groups (Bares 2009).

Conclusion: There is insufficient evidence to determine the long-term safety and efficacy of rTMS for the treatment of depression in patients who have failed at least one prior antidepressant medication. Results from one RCT suggest that rTMS may be effective at treating medication resistant depression; however, this trial does not address the durability of the effect. Additionally, studies addressing the efficacy of rTMS differ with regards to the duration of treatment and treatment parameters. More research is necessary to identify the ideal duration of treatment and treatment parameters.

Articles: Studies were selected for review if they included at least 25 subjects and assessed either the safety or efficacy of transcranial magnetic stimulation for the treatment of depression. Studies were excluded if they addressed the safety or efficacy of TMS for the treatment of conditions other than depression; if they compared different TMS applications to each other; or if they lacked a valid comparison group. Two recent meta-analyses were also identified, but not selected for review. One meta-analysis that examined the efficacy of slow frequency (≤ 1 Hz) rTMS for the treatment of depression was not selected as the trials included were all published before the 2009 review (Schutter 2010). The other meta-analysis was not selected for review because of methodological limitations (Slotema 2010). Additionally, the majority of the articles included in these meta-analyses were also included in a previously reviewed meta-analysis. Two RCTs were selected for review. The following studies were critically appraised: Bares M, Kopecek M, Novak T, et al. Low frequency (1-Hz), right prefrontal repetitive transcranial magnetic stimulation (rTMS) compared with venlafaxine ER in the treatment of resistant depression: A double-blind, single-center, randomized study. *J Affect Disord* 2009; 118:94-100. See [Evidence Table](#). George MS, Lisanby SH, Avery D, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: a sham-Controlled randomized trial. *Arch Gen Psychiatry* 2010; 67:507-516. See [Evidence Table](#).

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of treatment-resistant major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

08/17/2015: MTAC REVIEW

Repetitive Transcranial Magnetic Stimulation (rTMS)

Evidence Conclusion: The BCBS TEC assessment, published in January of 2014, established that the available evidence on the use of TMS therapy for depression does not meet the TEC criteria. More specifically, the TEC assessment was not able to make conclusions with regard to the effect of TMS on health outcomes, net health outcomes, and, as a result, was unable demonstrate that the technology was as beneficial as any established alternative and that results were attainable outside the investigational setting (BCBS 2014). Subsequent to the TEC assessment, a group of European experts made a conflicting conclusion regarding the efficacy of TMS for the treatment of depression. In their analysis of the literature, the European experts made a level A recommendation establishing the efficacy of high frequency rTMS of the left DLPFC in depression (Lefaucheur, André-Obadia et al. 2014).

Effectiveness: In the first meta-analysis, Gaynes and colleagues pooled data from 18 trials with the overall aim to evaluate the efficacy of rTMS in patients with treatment resistant depression. In all three primary outcomes (severity of depression symptoms, response rate, and remission) the investigators reported that rTMS was superior to sham leading to the conclusion that rTMS is a reasonable, effective treatment option in patients with treatment-resistant depression (Gaynes, Lloyd et al. 2014). The second meta-analysis, carried out by Kedzior and colleagues, focused more on the durability of the antidepressant effect. In their analysis, data from 16 studies involving 495 patients demonstrated only a small antidepressant effect during follow up (Kedzior, Reitz et al. 2015). **Safety:** The literature reports several common events to be associated with TMS therapy including problems at the site of coil placement, tension like headaches and light-headedness with the most serious event

reported being seizure. Overall, however, the technique appears to be relatively safe and reasonably well tolerated. Collectively, the body of published evidence relating to TMS therapy for depression is plagued with heterogeneity with a wide range of aims, outcomes and varying populations. To add to this, the technology is inherently limited by the lack of any established consensus regarding both the frequency and intensity of stimulation. Historically, TMS therapy for depression has failed MTAC criteria due to insufficient evidence. The current evidence remains conflicting and does not provide clear and convincing evidence that rTMS therapy is an effective and sustainable treatment option for depression. *Conclusion:* There is insufficient evidence to support the superiority of rTMS over antidepressants. There is evidence to support the short-term efficacy of rTMS over sham therapy. rTMS appears to be a relatively safe and well tolerated treatment.

Articles: The literature search identified an evidence-based guideline on the therapeutic use of rTMS in a variety of different conditions. (Lefaucheur, André-Obadia et al. 2014). In addition, a 2014 TEC (technology evaluation center) assessment produced by the Blue Cross and Blue Shield (BCBS) Association in association with Kaiser Permanente was identified (BCBS 2014). As a result, the literature search focused on updating the evidence base established by the guideline and TEC assessment (March 2014 through July 2015). The search yielded just over 200 publications including a variety of case series/reports, clinical trials, review articles, and meta-analyses. No studies were identified comparing rTMS as a monotherapy with antidepressants. The following studies were selected for critical appraisal: Gaynes BN, Lloyd S, Lux L, et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: a systematic review and meta-analysis. *J Clin Psychiatry*. 2014; 75(5):477-489. Kedzior KK, Reitz SK, Azorina V, et al. Durability of the antidepressant effect of the high-frequency repetitive transcranial magnetic stimulation (rTMS) in the absence of maintenance treatment in major depression: a systematic review and meta-analysis of 16 double-blind randomized, sham-controlled trials. *Depression and Anxiety*. 2015; 32:193-203.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

07/09/2018: MTAC REVIEW

Deep Repetitive Transcranial Magnetic Stimulation (dTMS)

MTAC Discussion and Outcome

Randomized controlled trial (Levkovitz et al, 2015. Evidence table 1)

This was multicenter sham-controlled double-blind randomized trial that examined the safety and efficacy of dTMS using H-coil versus a sham therapy in adult patients with a first or recurrent depression episode fulfilling the DSM-IV criteria for MDD. The study enrolled 233 patients 22-68 years of age who had failed 1-4 adequate antidepressant treatments for the current episode. Symptom severity was equivalent to a score of at least 20 on the Hamilton Depression Rating Scale (HDRS) with 21 questions (HAMD-21).

The patients were randomly assigned to receive an active dTMS using the H-coil or a sham treatment that used a placebo coil placed next to the H1-coil. The coil was selected for each patient with a pre-programmed card that was placed in a card reader attached to both-coils to maintain blinding of both the provider and the patient. All antidepressant medications were discontinued before the trial was begun.

Treatment was administered 5 days a week for 4 weeks, followed by twice-weekly treatment for up to 12 weeks. The treatment target was the dorsolateral prefrontal cortex on the left side with an intensity of 120% of the motor threshold with 2-s stimulations with 18 Hz followed by a 20-s pause, repeated 55 times over a total of ~20 minutes. The primary outcome was score change on the HAMD-21 after 4 weeks of therapy. Secondary outcomes were response and remission at 5 weeks, and adverse events. Response was defined as a reduction of ≥50% in the total HDRS-21 score compared to baseline; and remission was defined as a total HDRS-21 score <10.

233 patients were enrolled in the trial, N=212 were included in the ITT analysis, 181 (77%) in the per-protocol analysis. only 159 (68%) completed 5 weeks of the study and n=71 (30%) completed the 16 weeks.

Efficacy Levkovitz 2015 trial

The analysis showed that the treatment-group scored lower than the placebo group in the HDRS-21 from baseline to 5 weeks (primary outcome), The difference was not statistically significant according to the intention to treat analysis (ITT), but was statistically significant in the per-protocol analysis that included 77.7% of the patients enrolled (85% of those randomized to the treatment groups).

Validity of the trial

- The study was multicenter, randomized, controlled, double blinded, and had proper randomization and power analysis.
- dTMS was compared to sham therapy using an inactive coil, which is an important initial step to determine whether the treatment has a placebo effect. The trial, however, did not include a comparison arm with ECT or

other alternative treatment to determine whether dTMS has a superior, inferior, or equivalent effect on TRD compared to other established therapies.

- The results showed no significant difference in the primary outcome between the active dTMS and sham therapy according to the ITT analysis. The difference, however, was significant in the PP analysis which does not consider the dropout due to insufficient improvement and/or compliance, or tolerance.
- There were differences between the side effects and their rates reported to the FDA vs. those in the published article.
- Patients with psychosis, bipolar disorder, OCD, PTSD, any significant neurological disorder, increased risk of seizure or suicide were excluded from the study, which limits generalization of the results.
- The drop-out rate was high; only 68% of those initially enrolled completed the 5 weeks of treatment and less than one third completed the 16 weeks of the study, mainly due to insufficient improvement in the two study groups.
- The trial was supported by Brainsway the manufacturer of the dTMS H-coil; system, which is a potential source of reporting bias.

Meta-analysis: Kedzior et al, 2015 (Evidence table 2)

Kedzior and colleagues conducted a systematic review to investigate the acute antidepressant effect of dTMS using the H-coil in patients with MDD. The review included one RCT (Levkovitz, 2015) with 181 patients, and nine observational studies with a total of 162 patients. The observational studies very small (population sizes ranged from 6-29 participants); six were conducted in Israel, 2 in Italy and one in Canada. Most of the patients had treatment resistant unipolar depression and were on concurrent antidepressants (in only 2 studies dTMS was used as a monotherapy).

The authors pooled the results of the observational studies, and descriptively presented the results of the only one published RCT. The primary outcome was the change in standardized Hamilton Rating Scale for Depression scores, response rate, remission rate, and acceptability.

Validity of Kedzior et al's meta-analysis

- The meta-analysis had generally valid methodology and analysis. However, due to the lack of published RCTs, the authors pooled the results of 9 small observational studies with a total of 162 patients. The observational studies did not include a control or comparison group that received a sham treatment, ECT or any alternative therapy and the results were based on pre-post comparisons.
- The calculated overall effect sizes may be inflated by the possible placebo effect of the TMS.
- The studies included in the meta-analysis used different definitions for remission rates, which as well as the response rates varied widely between the studies. Response rates tended to be higher among patients on concurrent antidepressants and to increase with time, while remission rates tended to decrease over time, but did not seem to be affected by the concurrent use of antidepressants.
- The small sample sizes of the studies included, the short follow-up duration, and lack of control or comparison group, do not allow making any conclusion on the efficacy of dTMS, the durability of the reported results, or comparative effectiveness to ECT or other alternative therapies.

Conclusion:

- There is insufficient evidence to determine the comparative efficacy and safety of dTMS to ECT or other alternative therapies.
- There is limited evidence from one RCT showing that dTMS may have a superior short-term benefit compared to sham therapy.

The use of Repetitive transcranial magnetic stimulation (rTMS) for the treatment of major depression does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

03/2023: MTAT Review

Repetitive Transcranial Magnetic Stimulation (rTMS) for the Treatment of Bipolar Depression/Disorder (BPD)

Evidence Conclusion:

The Medical Technology Assessment Team (MTAT) reviewed the evidence assessment provided by SCPMG Evidence-Based Medicine Services on March 31, 2023, which concluded:

- In patients with BPD, there is very low-certainty evidence from one systematic review/metaanalysis (SR/MA) of RCTs and one additional RCT on the efficacy and safety of rTMS. The very low certainty of the evidence is due to the very low confidence in the effect estimate; and the true effect is likely to be substantially different from the estimate of effect.

The MTAT discussion with clinical expert input noted that despite the very low-certainty rating, the

current body of evidence did not report significant harms, with a very low rate of hypomania or mania switch. It was also noted that there is a high burden of suffering and poor quality of life for select BPD patients who are refractive to multiple treatment regimens and intolerant to electroconvulsive therapy (ECT). In these patients, rTMS may provide some benefit as an alternative treatment option. Discussions and development of recommendations on the management and potential use of rTMS for BPD are underway within SCPMG Psychiatry.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® or HCPC Codes	Description
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 delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
07/15/2009	06/01/2009, Reinstated criteria annual review for Medicare 4/4/2011 ^{MDCRPC} , 5/3/2011 ^{MDCRPC} , 2/7/2012 ^{MDCRPC} , 12/4/2012 ^{MDCRPC} , 09/01/2015 ^{MPC} , 07/05/2016 ^{MPC} , 05/02/2017 ^{MPC} , 03/06/2018 ^{MPC} , 03/05/2019 ^{MPC} , 03/03/2020 ^{MPC} , 03/02/2021 ^{MPC} , 03/01/2022 ^{MPC} , 03/07/2023 ^{MPC}	03/12/2024

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
10/03/2017	MPC approved to adopt MCG hybrid criteria for rTMS
10/10/2017	Migraine Headaches removed from indication
09/20/2018	Added MTAC review and denial language for dTMS
11/06/2018	MPC approved coverage for deep TMS
03/05/2019	MPC approved the recommendation to add the indication to include 18 y/o and older
03/03/2020	MPC approved the amended criteria to the existing hybrid TMS criteria (B-KP-801-T) to include additional indications for Behavioral Health Exclusions, Continued Therapy and Extension Therapy.
11/20/2023	Added March 2023 MTAT review for Repetitive Transcranial Magnetic Stimulation (rTMS) for the Treatment of Bipolar Depression/Disorder (BPD)
03/12/2024	MPC approved the revised clinical criteria for Transcranial Magnetic Stimulation (TMS) effective August 1 st , 2024. Requires 60-day Notice.