


MEDICAL POLICY	Transcranial Magnetic Stimulation (All Lines of Business Except Medicare)
Effective Date: 7/1/2021	Medical Policy Number: 269
 7/1/2021	Medical Policy Committee Approved Date: 11/2020; 5/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

All services related to behavioral health undergo Medical Director review and an individual determination of medical necessity is conducted.

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

The following documentation is required to determine the medical necessity of transcranial magnetic stimulation:

- The member’s current baseline depression score measured with an evidence-based depression rating scale (see [Policy Guidelines](#)).
- Documentation of member’s prior anti-depressant medication trials (including maximum dose used and frequency), or documentation of intolerance to anti-depressants.
- Documentation of psychotherapy trial including frequency, duration, and symptom response as measured by standardized rating scale.
- Proposed treatment plan for transcranial magnetic stimulation.

POLICY CRITERIA*Initial Treatment*

- I. Transcranial magnetic stimulation (TMS) using an FDA-approved device may be considered **medically necessary and covered** for the treatment of major depressive disorder (MDD) when **all** of the following criteria are met (A.-D.):
 - A. Diagnosis of severe major depressive disorder, documented by an evidence-based depression rating scale (see [Policy Guidelines](#)); **and**
 - B. Patient meets **at least one** of the following criteria (1.-2.):
 1. Depression symptoms have not responded to **at least 3** antidepressant medication trials from at least two different agent classes, at either the FDA-approved maximal dose or the maximally clinically-tolerated dose for a duration of at least 6 weeks; **or**
 2. The individual has a documented inability to tolerate the psychopharmacologic regimen described above; **and**
 - C. Depression symptoms have not responded to a 6-week trial of an evidence-based psychotherapy known to be effective in the treatment of MDD (unless contraindicated). Documentation must show that the trial did not significantly improve symptoms as measured by standardized rating scales (see [Policy Guidelines](#)); **and**
 - D. TMS is ordered and supervised by a psychiatrist or psychiatric nurse practitioner; **and**
 - E. The TMS treatment plan consists of up to 30 sessions (five days a week for six weeks) followed by six tapering sessions over three weeks (i.e. three treatments in first week, two treatments the next week, and one treatment the final week) for a maximum total of 36 sessions.
- II. Transcranial magnetic stimulation (TMS) for the treatment of major depressive disorder is considered **not medically necessary and not covered** when criterion I. above is not met, including but not limited to the following (A.-C.):
 - A. Transcranial magnetic stimulation maintenance therapy;
 - B. Use of TMS for treating indications other than major depressive disorders, including but not limited to, obsessive-compulsive disorder and migraine with aura;
 - C. Patient with active psychoses and/or catatonia where an immediate clinical response is needed.
 - D. Patient has one of the FDA contraindications for TMS (see [Policy Guidelines](#)).

Subsequent Treatment(s)

- III. Subsequent transcranial magnetic stimulation treatment(s) may be considered **medically necessary and covered** for a recurrence or an acute relapse of major depressive disorder when **both** of the following criteria are met (A.- B.):

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<p>A. Criterion I. above is met; and</p> <p>B. Previous TMS treatment(s) reduced clinical symptom severity, as evidenced by a 50% reduction on an evidence-based depression rating scale (see Policy Guidelines).</p> <p>IV. Subsequent transcranial magnetic stimulation treatments is considered not medically necessary and not covered for a recurrence or an acute relapse of major depressive disorder when criterion III. above is not met.</p> <p>Link to Policy Summary</p>
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POLICY GUIDELINES

Contraindications: Contraindications for transcranial magnetic stimulation include, but may not be limited to the following:

- Individuals who are actively suicidal;
- Individuals with a history of substance use, eating disorders, or post-traumatic stress disorder whose symptoms are the primary contributors to the clinical presentation;
- Individuals with a history of or risk factors for seizures during TMS therapy;
- Individuals with vagus nerve stimulators or implants controlled by physiologic signals, including pacemakers, and implantable cardioverter defibrillators;
- Individuals who are pregnant or nursing;
- Individuals who have conductive, ferromagnetic, or other magnetic-sensitive metals implanted in their head within 30 cm of the treatment coil (e.g. metal plates, aneurysm coils, cochlear implants, ocular implants, deep brain stimulation devices, and stents);
- Individuals who have active or inactive implants (including device leads), including deep brain stimulators, cochlear implants, and vagus nerve stimulators;
- Individuals with active psychoses or catatonia where a rapid clinical response is needed.

Depression Rating Scales: Examples of evidence-based rating scales include: Beck’s Depression Inventory (BDI), Hamilton Depression Rating Scale (HDRS), the Montgomery-Asberg Depression Rating Scale (MADRS), and the Patient Health Questionnaire-9 (PHQ-9).

CPT/HCPCS CODES

All Lines of Business Except Medicare	
Prior Authorization Required	
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

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90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
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DESCRIPTION

Indications

Major Depressive Disorder

Major depressive disorder (also referred to as clinical depression) is a common mental disorder that i mood, behavior, and various physical functions (e.g. appetite, sleep, concentration). Possible causes include a combination of biological, psychological and social sources, which may alter certain neural circuits in the brain. Resultant symptoms can include persistent feelings of sadness, irritability, fatigue and lack of interest in daily activities.

Migraine with Aura

Migraine with aura refers to sensory disturbances that occur shortly before a migraine attack. Disturbances can include seeing sparks, flashes of light, blind spots and other vision changes usually lasting between 20 to 60 minutes.

Obsessive Compulsive Disorder

Obsessive-Compulsive Disorder (OCD) is a common, chronic, menatl disorder in which a person has uncontrollable, recurring thoughts and/or behaviors that interfere with daily life. Common themes include a fear of germs or a need for objects to be arranged in a specific order .

Treatments

Transcranial Magnetic Stimulation

Repetitive transcranial magnetic stimulation (TMS or rTMS) is a noninvasive technique in which repetitive pulses of magnetic energy are applied to the scalp via a large electromagnetic coil. In this way, the electrical current in underlying cortical tissue is modulated. The goal of rTMS is to influence activity in areas of the brain involved in mood regulation, with the goal of shortening the duration and/or severity of depressive episodes. The procedure may be used to augment current pharmacotherapy or as a primary treatment strategy.¹

Maintenance Transcranial Magnetic Stimulation

Maintenance therapy refers to the continual use of TMS for the treatment of depression, with the goal of preventing future depressive episodes.

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REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of transcranial magnetic stimulation for the treatment of major depression disorder. Below is a summary of the available evidence identified through July 2020.

Major Depressive Disorder

Systematic Reviews

- In 2016 (updated 2020), Hayes conducted a systematic review evaluating the safety and efficacy of high-frequency left repetitive transcranial magnetic stimulation (HFL- rTMS) for treatment-resistant major depressive disorder (TRD). In total, 15 sham-controlled, randomized trials were included for review.¹ Sample sizes ranged from 30 to 301. Outcomes of interest included depression symptom scale scores, response rates, remission rates and adverse events. Follow-up ranged from 2 weeks to 6 months after the end of treatment.

Findings from 3 studies were mixed regarding rTMS as monotherapy for TRD on depression symptom scores. Patients receiving rTMS experienced response rates ranging from 15% to 50%, superior to the 0% to 12% range experienced by patients receiving sham treatments. Remission rates were also superior for rTMS patients (14% to 33% remission vs. 0% to 5.5% for the sham group.) Findings were inconsistent regarding the efficacy of rTMS as add-on therapy in medication-stable patients. Eight studies supported improved depression symptoms with rTMS, whereas 4 studies concluded that symptoms may not be improved with rTMS. Across 11 studies, response ranges were 0% to 72.7% for rTMS and 0% to 27.5% for sham treatment. Remission rates ranged from 4.5% to 54.5% for rTMS while sham-treated comparators rates ranged from 0% to 10% among 6 studies. The magnitude of difference between active and sham groups in post-treatment scores or change from baseline to posttreatment evaluation was generally small. A persistence of benefits for 1 week to 3 months was supported by findings from 4 RCTs, but relapse in responders was high in the only study to follow patients for more than 3 months. Evidence was judged insufficient to establish specific patient selection criteria for rTMS as a monotherapy or add-on therapy for treatment-resistant MDD.

Hayes assigned rTMS a “C” rating (potential but unproven benefit) for its use as either a monotherapy or add-on therapy for reducing depression symptoms in patients with treatment-resistant depression. Evidence was judged insufficient for the use of rTMS as a maintenance therapy to prevent relapse in patients who had a major depressive episode that remitted with treatment.

- In 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) published a systematic review assessing the safety, efficacy and cost-effectiveness of repetitive transcranial magnetic stimulation for the treatment of depression.² Independent investigators systematically searched the literature through May 2019, identified eligible studies, assessed study quality and

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extracted data. In total, three systematic reviews and 5 RCTs were included for review. Two of the systematic reviews included only sham comparators, while the third included pharmacological, electro-convulsive therapy, and sham comparators. One systematic review reported a difference in depression rating score of -3.6 points between rTMS and sham treatments. A second study reported a weighted mean difference in HDRS scores between rTMS and sham of 2.31 points in favor of rTMS. Investigators concluded that the effect of rTMS was clinically relevant in two of the three systematic reviews. On the basis of “weak evidence,” the Agency recommended use of rTMS for treatment-resistant depression without endorsement of a specific protocol. Limitations of the reviewed studies’ included the lack of randomization and allocation concealment, unclear reporting of statistical analyses, lack of intention-to-treat analysis, differences in baseline patient characteristics and lack of long-term follow-up.

- In 2016 (updated 2020), Hayes conducted a systematic review evaluating the safety and efficacy of high-frequency left repetitive transcranial magnetic stimulation (HFL-rTMS) versus other neurostimulation approaches for treatment-resistant depression.³ For HFL-rTMS versus electroconvulsive studies (ECT), sample sizes ranged from 32 to 73 patients (314 total patients); for HFL-rTMS versus bilateral rTMS studies, sample sizes ranged from 66 to 121 patients (255 total patients). In total, 10 RCTs were included for review. Outcomes of interest included depression symptom scale scores, response rates, remission rates, and adverse events. Follow-up was 6 months.

The quality of studies ranged from “poor” to “fair.” Findings from 6 studies were mixed regarding the comparative effectiveness of HFL-rTMS and ECT. Four studies reported no significant difference between HFL-rTMS and ECT with regard to depression symptom scores, nor did groups differ on response rates (2 studies) or remission rates (3 studies). However, 2 studies reported greater symptom improvement among ECT patients. In addition, ECT was significantly favored over HFL-rTMS for response rate (1 study) and remission rate (1 study). Findings from 3 studies comparing efficacy between HFL-rTMS versus bilateral rTMS were mixed. Two studies found no difference in symptom improvement between HFL and bilateral rTMS, while 1 study found better improvement with bilateral rTMS. Response and remission rates did not differ between HFL-rTMS and ECT in 2 studies and 1 study, respectively. However, rate of response was significantly higher among bilateral rTMS patients in 1 study, as was remission in another study. Evidence was judged insufficient to establish specific patient selection criteria. On the basis of low-quality evidence, investigators concluded that HFL-rTMS may offer comparable therapeutic benefit relative to ECT and bilateral rTMS for relief of TRD as measured by symptoms of depression and achievement of treatment response and symptom remission. Hayes gave “D2” rating (“insufficient evidence”) for the use of HFL-rTMS combined with ECT compared to ECT alone for the treatment of depression.

- In 2016, Health Quality Ontario conducted a systematic review assessing the safety and efficacy of repetitive transcranial magnetic stimulation for the treatment of depression.⁴ Independent investigators systematically searched the literature through May 2019, identified eligible studies, assessed study quality and extracted data. In total, 23 RCTs comparing rTMS with sham,

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and six RCTs comparing rTMS with electroconvulsive therapy (ECT) were included for review. Trials of rTMS versus sham showed a significant improvement in depression scores with rTMS, although this improvement was smaller than the pre-specified clinically important treatment effect. There was a 10% absolute difference between rTMS and sham in the rates of remission or response. Risk ratios for remission and response were 2.20 and 1.72 respectively, favoring rTMS. No publication bias was detected. Trials of rTMS versus ECT showed a statistically and clinically significant difference between rTMS and ECT in favor of ECT. Investigators concluded that evidence favored ECT over rTMS. Repetitive transcranial magnetic stimulation was determined to produce a small short-term effect for improving depression in comparison with sham, but due to the lack of studies with long-term follow-up, the durability of these improvements is unclear.

- In 2014, the Washington State Health Care Authority published a systematic review addressing nonpharmacologic treatments for treatment-resistant depression.⁵ Repetitive transcranial magnetic stimulation (rTMS) was among the evaluated treatments. Independent investigators systematically searched the literature through November 2013, identified eligible studies, assessed study quality and extracted data. Outcomes of interest included treatment response, remission, depression severity, functional status, and quality of life. In total, 15 systematic reviews, 23 RCTs, 1 post-hoc analysis of RCTs and 3 economic evaluations were included for review. Evidence from 5 low-quality RCTs suggested that rTMS may be as effective as electroconvulsive therapy under certain circumstances, but not under others. On the basis of low-quality evidence, investigators concluded that there was no significant difference between rTMS and sham stimulation. Nonetheless, the overall body of evidence was judged to be consistent with regard to direction of the results and authors stated that rTMS may serve primarily to accelerate recovery. Optimal treatment parameters were not identified for the use of rTMS, and no “moderate” or “high” quality evidence established an association between the treatment effect of rTMS and patient characteristics.

Non-Covered Treatments

Maintenance Therapy

In 2014, Dunner and colleagues evaluated the safety and efficacy of rTMS maintenance therapy for patients with treatment-resistant depression.⁶ In total, 205 patients across 42 sites were assessed at 12-month follow-up. Of these 205, 120 patients (58%) 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 at 1-year follow-up. Investigators concluded that maintenance TMS leads to significant reductions in depressive symptoms at but called for additional research to validate findings.

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Obsessive Compulsive Disorder

In 2019 (updated 2020), Hayes conducted a systematic review assessing the safety and efficacy of repetitive transcranial magnetic stimulation (rTMS) for the treatment of obsessive-compulsive disorder (OCD).⁷ In total, 13 RCTs and 1 crossover study were included for review. Sample sizes ranged from 21 to 60 patients; follow-up was recorded at 12 weeks following the end of treatment. The primary outcome of interest was the improvement in scores on various obsessive compulsive scales (e.g. Y-BOCS) rating scales.

Results from 8 trials favored rTMS over sham for improvements in depression rating scale scores from baseline to end of treatment or 12-week follow-up. The remaining 6 studies reported either mixed results, or no significant difference findings between treatment groups. Of 6 studies that evaluated clinically meaningful reduction in depression rating scale score, 2 studies reported that significantly greater numbers of patients in the rTMS group achieved clinically meaningful reductions, 2 studies reported that more patients in the rTMS group achieved clinically meaningful improvement. It is unclear, however, if this difference was statistically significant. Two studies found no differences in the number of patients achieving clinically meaningful improvement. Findings were similar between both high- and low-frequency treatments.

The overall quality of evidence was assessed as “low.” Limitations included the lack of follow-up beyond 3 months, questions regarding the effectiveness of rTMS over sham treatment, heterogeneous patient characteristics and treatment parameters, mixed findings and a lack of comparative effectiveness data. Additional uncertainty remains regarding optimal treatment parameters and patient selection criteria. Hayes ultimately assigned a “C” rating (potential but unproven benefit) for the use of rTMS as an add-on therapy for patients with OCD who have had inadequate responses to at least one prior treatment. Evidence was judged “insufficient” to support the use of rTMS as a monotherapy for OCD.

Migraine with Aura

Several recent systematic reviews have assessed the safety and efficacy of transcranial magnetic stimulation for the treatment of migraine with aura.⁸⁻¹⁰ While results indicate that rTMS leads to reductions in headache frequency, duration, intensity and functional impairments, each study called for additional high-quality RCTs with standardized protocols in order to validate treatment effects.

CLINICAL PRACTICE GUIDELINES

National Network of Depression Centers/American Psychiatric Association

In 2018, the National Network of Depression Centers and American Psychiatric Association published consensus recommendations for the clinical application of repetitive transcranial magnetic stimulation (rTMS) in the treatment of depression.¹¹ On the basis of a systematic review of evidence and expert opinion, investigators issued the following recommendations:

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- The expert opinion is that rTMS is appropriate as a treatment in patients with MDD even if the patient is medication resistant or has significant comorbid anxiety.
- There is no one recommended maintenance antidepressant strategy for patients after a beneficial rTMS acute course. Rather, it is recommended that the following available evidence-based antidepressant strategies be used after successful acute rTMS treatment: repeat rTMS, pharmacotherapy, manualized psychotherapy, exercise and combination of those treatments. Further research is needed to develop evidenced-based antidepressant maintenance strategies following acute clinical benefits with rTMS.
- Regarding allowable psychotropic medications during TMS treatment the consensus statement indicates that the safety guidelines for rTMS were determined in study participants who were largely free of antidepressant medications. While it is possible that psychotropic medication can affect the motor threshold, there are no known absolute contraindications to psychotropic medication usage during rTMS.
- FDA approval of rTMS is limited to adults with MDD. However, there is evidence of safe therapeutic use and clinical benefit of rTMS in adolescents with mood disorders, women with perinatal depression and other neuropsychiatric disorders including bipolar disorder, panic disorder, obsessive-compulsive disorder, depersonalization disorder, posttraumatic stress disorder and schizophrenia. However, there is insufficient evidence to support routine clinical rTMS use in these populations.
- The rTMS prescriber should be a clinician with prescriptive privileges who is knowledgeable about, trained, and credentialed in rTMS. Such training should include proficiency in all aspects of the rTMS procedure. Each service should develop its own policy regarding how many times a prescriber must obtain motor threshold or treat a patient before recredentialing of that prescriber.
- The TMS device operator should be a clinical professional who independently administers rTMS under the supervision of the rTMS prescriber. The operator should be trained in assessing the MT and administering the treatment. At all times, the TMS device operator monitors the patient during treatment administration, especially for adverse events, and ensures contact between the TMS coil and the patient’s scalp. The operator should be trained to understand evidence of cortical excitation (ie, movements in the hand during the procedure) and be proficient in managing a potential seizure. The operator must also be able to independently make routine adjustments (eg, move the TMS coil) and have specific guidelines as to when to contact the rTMS prescriber.
- Examples of TMS device operators include certified medical assistants, medical technicians with relevant experience, physician assistants, and nurses. If the TMS clinical practice is governed within a hospital setting, the TMS device operator should be approved by the hospital bylaws.

Department of Veterans Affairs/Department of Defense (VA/DoD)

In 2016, the VA/DoD published a clinical practice guideline addressing the management of major depressive disorder.¹² On the basis of weak evidence, investigators suggested offering treatment with repetitive transcranial magnetic stimulation (rTMS) for treatment during a major depressive episode in patients with treatment-resistant major depressive disorder.

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National Institute for Health and Care Excellence (NICE)

In 2015, the NICE published an interventional procedures guidance addressing transcranial direct magnetic stimulation for the treatment of depression.¹³ Investigators made the following recommendations:

- The evidence on repetitive transcranial magnetic stimulation for depression shows no major safety concerns. The evidence on its efficacy in the short-term is adequate, although the clinical response is variable. Repetitive transcranial magnetic stimulation for depression may be used with normal arrangements for clinical governance and audit.
- During the consent process, clinicians should, in particular, inform patients about the other treatment options available, and make sure that patients understand the possibility the procedure may not give them benefit.
- NICE encourages publication of further evidence on patient selection, details of the precise type and regime of stimulation used, the use of maintenance treatment and long-term outcomes.

American Psychiatric Association (APA)

In 2015, the APA published a practice guideline for the treatment of patients with major depressive disorder. Authors stated that repetitive TMS may be considered, although with less evidence to support relative electroconvulsive therapy.

POLICY SUMMARY

Low-quality but consistent evidence supports the use of (repetitive) transcranial magnetic stimulation (TMS) for the treatment of major depressive disorder. At 6-month follow-up, data indicate that TMS patients experience superior response and remission rates relative to patients undergoing sham therapy, and comparable rates to patients undergoing other forms of neurostimulation. Specific patient selection criteria for TMS as a monotherapy, or add-on therapy, remain unclear, although an emerging consensus holds that providers should consider TMS for patients who have failed to respond to at least two anti-depressant medication trials. Despite a lack of studies with long-term follow-up, 4 evidence-based clinical practice guidelines also recommend the use of TMS.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

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The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Food and Drug Administration (FDA)

The following transcranial magnetic stimulation have received FDA clearance. This list may not be comprehensive.

Major Depressive Disorder

- Brainsway H-Coil Deep TMS System¹⁴
- Neurostar TMS Therapy¹⁵
- Rapid2 Therapy System¹⁶
- Neurosoft TMS¹⁷

Obsessive Compulsive Disorder

- Brainsway Deep Transcranial Magnetic Stimulation System¹⁸

Migraine with Aura

- Cerena Transcranial Magnetic Stimulator (TMS) Device¹⁹
- SpringTMS^{®20}

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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