Transcranial Magnetic Stimulation

MEDICAL POLICY NUMBER: 269

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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 Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. 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. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP 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.

Transcranial Magnetic Stimulation: Guideline Note 102

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: Transcranial magnetic stimulation (TMS) using an FDA-approved device is not recommended for patients under 18 years of age.

Initial Treatment

I. Transcranial magnetic stimulation (TMS) using an FDA-approved device may be considered **medically necessary** for the treatment of major depressive disorder (MDD) when **all** of the following criteria are met (A.-F.):

   A. Patient has received a diagnosis of major depressive disorder (MDD), as defined by all of the following, occurring within the same **2-week period** (1.-3.):
      1. Patient has either of the following two symptoms (a.-b.):
         a. Depressed mood; **or**
         b. Markedly diminished interest or pleasure in usual activities; **and**
      2. Patient has at least **four** of the following symptoms (a.-g.):
         a. Significant change in weight and/or appetite;
         b. Insomnia or hypersomnia;
         c. Psychomotor agitation or retardation;
         d. Fatigue or loss of energy;
         e. Feelings of worthlessness or excessive or inappropriate guilt;
         f. Slowed thinking or impaired concentration;
         g. Recurrent thoughts of death or suicidal ideation or a suicide attempt; **and**
      3. All of the following criteria are met (a.-d.):

a. Symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functions; **and**
b. The episode is not attributable to the physiological effects of a substance or to another medical condition; **and**
c. The occurrence of the major depressive episode is not better explained by schizoaffective disorder, schizophrenia, schizophreniform disorder, delusional disorder, or other specified and unspecified schizophrenia spectrum and other psychotic disorders; **and**
d. The patient has never has a manic or a hypomanic episode (unless episode(s) were substance-induced or are attributable to the physiological effects of another medical condition); **and**

B. Diagnosis of major depressive disorder is documented as "severe" by an evidence-based depression rating scale (see Policy Guidelines); **and**
C. Patient meets **at least one** of the following criteria (1.-2.):
    1. Depression symptoms of the current episode (i.e. beginning within the past 36 months) have not responded to **at least 3** antidepressant medication trials (approved by the FDA for the treatment of MDD) 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 (see Policy Guidelines); **or**
    2. The individual has a documented inability to tolerate three antidepressant medication trials from at least two agent classes as described above; **and**
D. Therapist's documentation from the current depressive episode (i.e. within the past 36 months) showing that 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) as measured by standardized rating scales (see Policy Guidelines); **and**
E. TMS is ordered by a psychiatrist or psychiatric nurse practitioner who supervises the treatment (i.e. is present in the area and immediately available during treatment); **and**
F. 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** when criterion I. above is not met, including but not limited to the following (A.-E.):

A. Transcranial magnetic stimulation maintenance therapy;
B. Accelerated transcranial magnetic stimulation;
C. Use of TMS for treating indications other than major depressive disorders, including but not limited to, obsessive-compulsive disorder, migraine with aura, persistent depressive disorder (i.e. dysthymia);
D. Patient with active psychoses and/or catatonia where an immediate clinical response is needed;
E. 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** for a recurrence or an acute relapse of major depressive disorder when **all** of the following criteria are met (A.- C.):
   A. Current episode is severe (see Policy Guidelines); **and**
   B. Criteria for initial TMS therapy were met prior to the first course of TMS (see criterion I. above); **and**
   C. Previous TMS treatment(s) reduced clinical symptom severity, as evidenced by a 50% reduction on an evidence-based depression rating scale (see Policy Guidelines), and this improvement was maintained for at least 2 months after the prior TMS treatment course.

IV. Subsequent transcranial magnetic stimulation treatments are considered **not medically necessary** for a recurrence or an acute relapse of major depressive disorder when criterion III. above is not met.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

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.

DEFINITIONS

Antidepressant Medication Trials – The addition of an augmenting agent to a medication trial would be considered an additional trial.

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 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)
  - 1 to 10 - Not depressed
  - 11 to 16 - Mild mood disturbance
  - 17 to 20 - Borderline clinical depression
  - 21 to 30 - Moderate depression
  - 31 to 40 – Severe depression
  - Over 40 -Extreme depression
- Hamilton Depression Rating Scale (HDRS)
  - 0 to 7: Not depressed
  - 8 to 13: Mild (subthreshold)
  - 14 to 18: Moderate (mild)
  - 19 to 22: Severe (moderate)
  - >23: Very severe (severe)
- Montgomery-Asberg Depression Rating Scale (MADRS)
  - 0 to 6: Not depressed
  - 7 to 19: Mild Depression
  - 20 to 34: Moderate Depression
  - 35 to 60: Severe Depression
- Patient Health Questionnaire-9 (PHQ-9)
  - 0 to 4: Not depressed
  - 5 to 9: Mild depression
  - 10 to 14: Moderate depression
  - 15 to 19: Moderately severe depression
  - 20 to 27: Severe depression

BACKGROUND

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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Several transcranial magnetic stimulation devices have received FDA clearance. This list may not be comprehensive. Please refer to the FDA's 510(k) Premarket Notification website using product code "OBP."[2]

Major Depressive Disorder

- Brainsway H-Coil Deep TMS System
- Neurostar TMS Therapy
- Horizon 3.0 TMS Therapy
- MagVita TMS Therapy System w/Theta Burst Stimulation
- Nextstim Navigated Brain Therapy (NBT) System 2
- Rapid2 Therapy System
- Neurosoft TMS

Obsessive Compulsive Disorder

- Brainsway Deep Transcranial Magnetic Stimulation System

Migraine with Aura

- Cerena Transcranial Magnetic Stimulator (TMS) Device
- SpringTMS®

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

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 October 2024.

Major Depressive Disorder

Systematic Reviews

- In 2024, Hayes conducted a systematic review evaluating the safety and efficacy of theta burst stimulation (TBS) for treatment-resistant unipolar depression in adults.[3] The body of evidence suggests that TBS is potentially effective for reducing the symptoms of depression, including suicidality, and improving health-related quality of life (HRQOL) among adult patients with treatment-resistant MDD; however, questions remain regarding rates of response and remission and the durability of treatment effect is uncertain. Most of the included studies found that rates of clinical response and remission at the end of TBS treatment ranged from 35% to 55% and 18% to 30%, respectively. Rates of response and remission during posttreatment follow-up were inconsistent across studies. The evidence largely showed that TBS led to significant improvement of depression symptoms when compared with pretreatment values or with sham therapy. Outcomes related to HRQOL and suicidality also appeared to improve with TBS, but few studies reported those outcomes. Despite positive results, the overall quality of the body of evidence for TBS was rated as low. The overall quality rating was downgraded due to individual study limitations, high degree of heterogeneity in treatment parameters and outcome measures, short length of follow-up and uncertainty regarding duration of benefit, and undetermined ideal patient selection criteria. Authors awarded a "C" rating (potential but unproven benefit), concluding that studies that evaluate longer-term outcomes and assess protocol/patient selection optimization are needed to address limitations in studies conducted to date.

- In 2021, 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 2021, ECRI conducted a systematic review assessing the safety and efficacy of theta burst transcranial magnetic stimulation for treating adults with major depressive disorder.[4] Authors assessed 1 systematic review (SR)) with meta-analysis and 3 RCTs reporting on 1 or more of the following outcomes: depression symptom change, response (often defined as ≥50% reduction compared with baseline Hamilton Depression Rating Scale [HDRS]-17 score) and remission (often defined as HDRS-17 score ≤7), acceptability, and adverse events. Authors concluded that evidence supporting the procedure was "somewhat favorable." The systematic review described several study limitations: patients in RCTs had varying degrees of therapy resistance at baseline; 8 of 10 included studies applied TBS to augment medications, limiting the ability to isolate a direct effect of rTMS in terms of response and remission rates. No study follow-up period exceeded 6 months. Also, 4 of the 10 included studies in the SR enrolled patients with bipolar depression. The Chou et al. 2020 RCT allowed antidepressant use during the 6-month follow-up period. This RCT is at risk of bias due to small sample size and single-center focus. Blumberger et al. 2020 lacked a sham control group, included 24 patients who met varying exclusion criteria, and used MRI-guided neuronavigation during treatment sessions, an approach that is not available in most rTMS clinics. Lastly, included studies were conducted in several different countries, and findings of individual studies may not generalize to those of healthcare practices outside the health systems or countries from which the patient data were derived.

- 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.[5] Independent investigators systematically searched the literature through May 2019, identified eligible studies, assessed study quality and 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 2021, 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.[6] 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.[7] 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, 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 2023, the Washington State Health Care Authority published a systematic review addressing Transcranial Magnetic Stimulation for Treatment of Selected Behavioral Disorders.[8] Reviewers included 64 RCTS, 61 of which provided evidence on efficacy outcomes and 58 provided safety outcomes. They concluded the following,

  > "This HTA examined the efficacy, safety, and cost-effectiveness of active TMS compared to sham TMS for selected behavioral health conditions. TMS has low SOE for benefit in OCD at posttreatment and moderate to high SOE for benefit in MDD. Evidence for benefit for the other conditions (GAD, PTSD, smoking cessation, SUD) ranges from insufficient to low for benefit depending on the outcome assessed. Data on the efficacy of TMS at longer follow-up assessments were lacking across all conditions. There was less robust evidence for safety outcomes, although studies generally reported fewer adverse events for sham TMS; few serious adverse events were reported for either active or sham TMS. Evidence is lacking with respect to cost-effectiveness outcomes."

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.[9] 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.

Accelerated Transcranial Magnetic Stimulation

In 2023, Hayes published an evolving evidence review assessing the safety and efficacy of accelerated repetitive transcranial magnetic stimulation for treatment of depression.[10] Authors concluded that evidence from clinical studies, systematic reviews, and policies and guidelines addressing accelerated repetitive transcranial magnetic stimulation (rTMS) suggest that the protocol is safe; however, there is

not enough evidence to support it as a recommended treatment. Treatment parameters varied greatly in the eligible clinical studies, which may ultimately impact proponents' claims that an accelerated treatment protocol would reduce patient burden.

Obsessive Compulsive Disorder

- In 2021, ECRI conducted an evidence review assessing the safety and efficacy of TMS for the treatment of adults with obsessive-compulsive disorder (OCD).[11] Evidence from a systematic review (SR) with meta-analysis of 26 very small randomized controlled trials (RCTs) and 3 additional RCTs indicated TMS (different protocols, frequencies, and brain targets) improves OCD symptoms in the short term (up to 4-weeks post-treatment) more than sham stimulation for some patients with OCD whose condition has not responded to drug therapies. Authors determined that the studies assessed too few patients to determine whether benefits are maintained after 6 or more weeks of treatment. Studies in the SR were also judged as having assessed too few patients per stimulation frequency and intensity in relation to brain target location to be conclusive on optimal treatment regimens. Authors concluded that evidence supporting TMS for the treatment of OCD was "inconclusive" and that large, multicenter RCTs with at least 6-month follow-up are required to confirm these findings treatment parameters.[11]

- In 2022, Hayes conducted a systematic review assessing the safety and efficacy of repetitive transcranial magnetic stimulation (rTMS) for the treatment of obsessive-compulsive disorder (OCD).[12] 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 meaningfully 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.[13-15] 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.[16] On the basis of a systematic review of evidence and expert opinion, investigators issued the following recommendations:

- 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 2022, the VA/DoD published a clinical practice guideline addressing the management of major depressive disorder.[17] 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 who have experienced partial response or no response to an adequate trial of 2 or more pharmacologic treatments.

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.

National Institute for Health and Care Excellence (NICE)

Obsessive Compulsive Disorder

In 2020, the NICE published clinical practice guidelines addressing TMS for the treatment of obsessive-compulsive disorder (OCD). Authors stated that evidence supporting the efficacy of TMS for the treatment of OCD is "inadequate in quantity and quality" and that the procedure should only be used in the context of research.[18]

Depression

In 2015, the NICE published an interventional procedures guidance addressing transcranial direct magnetic stimulation for the treatment of depression.[19] 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.

EVIDENCE 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.

BILLING GUIDELINES AND CODING

Note: Physician Assistants (PAs) and Nurse Practitioners (NPs) may not bill independently for TMS services. These services must be billed "incident to" a supervising physician, in accordance with applicable billing guidelines. (This clarification applies specifically to the administration of daily TMS sessions. The initial evaluation and treatment planning, however, must be performed directly by the supervising psychiatrist or PMHNP and cannot be delegated or conducted under supervision (see criterion I.E. above)).

CODES*		
CPT	0858T	Externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials with automated report
	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 day
	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
	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

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
1/2024	Q1 2024 code updates.
2/2024	Updated “Policy Guidelines” and criterion III.

6/2024	Interim update. Updated “Policy Guidelines.”
7/2024	Q3 2024 code set update.
2/2025	Annual update. Updated criterion III.