# **Medical Policy**

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

## **COVERAGE CRITERIA**

**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 <u>Policy Guidelines</u>); **and**
- C. The patient is age 15 years or older; and
- D. Patient meets at least one of the following criteria (1.-2.):
  - Depression symptoms of the current episode (i.e. beginning within the past 36 months) have not responded to <u>at least 2</u> 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 <u>Policy Guidelines</u>); or
  - 2. The individual has a documented inability to tolerate two antidepressant medication trials from at least two agent classes as described above; **and**
- E. 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 <a href="Policy Guidelines">Policy Guidelines</a>); and
- F. 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**
- G. 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) using an FDA-approved device may be considered **medically necessary** for the treatment of obsessive-compulsive disorder (OCD) when **all** of the following criteria are met:
  - A. The patient has received a diagnosis of OCD; and
  - B. Diagnosis of OCD is documented as "moderate" or above by an evidence-based rating scale (see Policy Guidelines); and
  - C. The patient is age 18 years or older; and
  - D. The individual has failed treatment with or documented inability to tolerate three medications from the following: clomipramine/Anafranil; any SSRIs (selective serotonin reuptake inhibitors; 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.

- III. Transcranial magnetic stimulation (TMS) for the treatment of major depressive disorder or obsessive-compulsive disorder is considered **not medically necessary** when criterion I. above is not met for major depressive disorder and when criterion II. above is not met for obsessive-compulsive disorder, 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, 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)

- IV. Subsequent transcranial magnetic stimulation treatment(s) may be considered **medically necessary** for a recurrence or an acute relapse of major depressive disorder or obsessive-compulsive disorder (OCD) 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 rating scale for depression or OCD (see <u>Policy Guidelines</u>), and this improvement was maintained for at least 2 months after the prior TMS treatment course.
- V. Subsequent transcranial magnetic stimulation treatments are considered **not medically necessary** for a recurrence or an acute relapse of major depressive disorder or obsessive-compulsive 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
  - o 11 to 16 Mild mood disturbance
  - o 17 to 20 Borderline clinical depression
  - 21 to 30 Moderate depression
  - o 31 to 40 Severe depression
  - Over 40 -Extreme depression
- Hamilton Depression Rating Scale (HDRS)
  - o 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)
  - o 0 to 6: Not depressed
  - o 7 to 19: Mild Depression
  - o 20 to 34: Moderate Depression
  - o 35 to 60: Severe Depression
- Patient Health Questionnaire-9 (PHQ-9)
  - o 0 to 4: Not depressed
  - o 5 to 9: Mild depression
  - o 10 to 14: Moderate depression
  - o 15 to 19: Moderately severe depression
  - o 20 to 27: Severe depression

Obsessive-compulsive disorder Rating Scales: One example of an evidence-based rating scale is:

- Yale-Brown Obsessive Compulsive Scale (Y-BOCS)
  - o 0 to 7: None
  - o 8 to 15: Mild
  - o 16 to 23: Moderate
  - 24 to 31: Severe
  - o 32 to 40: Extreme

#### **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, mental 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.<sup>1</sup>

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."<sup>2</sup>

#### 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 2025.

## 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.<sup>3</sup> 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. 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. <sup>4</sup> 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. 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.<sup>6</sup> 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. 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.<sup>8</sup> 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."

#### **Obsessive Compulsive Disorder**

• In 2019 and updated 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). 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.

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.

In 2025, Hayes conducted an additional evidence analysis research brief to summarize additional evidence that has come out since the 2019 review. Among ten identified additional papers, they found that there is moderate evidence supporting the use of rTMS for reducing symptoms of obsessive-compulsive disorder (OCD). Multiple randomized controlled trials and systematic reviews have reported statistically significant improvements in OCD severity, particularly when rTMS is targeted to specific brain regions such as the dorsolateral prefrontal cortex and presupplementary motor area. Limitations include small sample sizes, variability in stimulation protocols and target sites, heterogeneity in study designs, and potential risk of bias or publication bias across several trials.

• In 2021, ECRI conducted an evidence review assessing the safety and efficacy of TMS for the treatment of adults with obsessive-compulsive disorder (OCD). <sup>11</sup> 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

#### **Non-Covered Treatments**

#### Maintenance Therapy

- In 2025 Hayes published a Health Technology Assessment evaluating the use of maintenance repetitive transcranial magnetic stimulation (rTMS) for preventing recurrence of major depressive disorder (MDD) in adults.<sup>12</sup> The evidence was rated D (very low quality), indicating insufficient data to support efficacy or safety. Most studies were small, poorly designed, and showed inconsistent results, with rTMS performing similarly to sham or usual care. No definitive patient selection criteria were identified, and all reviewed payer policies consider maintenance rTMS investigational.
- In 2014, Dunner and colleagues evaluated the safety and efficacy of rTMS maintenance therapy for patients with treatment-resistant depression. 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. <sup>14</sup> 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.

# Migraine with Aura

Several recent systematic reviews have assessed the safety and efficacy of transcranial magnetic stimulation for the treatment of migraine with aura. <sup>15-17</sup> 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**

<u>National Network of Depression Centers/The Clinical TMS Society/The International Federation of Clinical Neurophysiology</u>

In 2025, the National Network of Depression Centers, The Clinical TMS Society, and the International Federation of Clinical Neurophysiology endorsed a comprehensive update of the previously published 2018 consensus statement by the National Network of Depression Centers on the use of transcranial magnetic stimulation (TMS) in the treatment of depression. On the basis of a systematic review of evidence and expert consensus, investigators issued the following updated recommendations for the clinical application of repetitive transcranial magnetic stimulation (rTMS) in the treatment of depression:

- Expert consensus affirms that rTMS is appropriate for patients with major depressive disorder (MDD), including those with treatment-resistant depression and comorbid anxiety. Evidence supports its use earlier in treatment algorithms, with some studies showing superior outcomes compared to medication switches or augmentation strategies.
- There is no single recommended maintenance strategy following a successful acute rTMS course. Evidence supports the use of repeat rTMS, pharmacotherapy, manualized psychotherapy, exercise, and combinations thereof. Clustered maintenance protocols (e.g., multiple sessions over a few days monthly) show promise, but optimal scheduling remains under investigation.
- Psychotropic medications may influence motor threshold variability, but there are no absolute
  contraindications to their use during rTMS. Benzodiazepines may be associated with reduced
  efficacy, while psychostimulants and SSRIs may enhance outcomes. Clinicians should monitor for
  medication-related changes in cortical excitability and adjust motor threshold assessments
  accordingly.
- FDA approval of rTMS has expanded to include adolescents aged 15 and older with MDD.
   Evidence supports safe and potentially effective use in adolescents, older adults, and peripartum populations. However, routine use in children under 15, individuals with psychotic depression, and other neuropsychiatric conditions (e.g., PTSD, OCD, schizophrenia) remains investigational due to limited data.
- The rTMS prescriber should be a clinician with prescriptive authority and formal training in rTMS. Training should include proficiency in motor threshold determination, coil targeting, protocol selection, and management of adverse events. Credentialing should be maintained through ongoing education and clinical experience.
- The TMS device operator should be a trained clinical professional who administers rTMS under supervision. Operators must be competent in motor threshold assessment, coil positioning, patient monitoring, and emergency response (e.g., seizure management). They should follow clear protocols for when to escalate concerns to the supervising clinician.
- Examples of qualified TMS device operators include certified medical assistants, medical technicians, physician assistants, and nurses. In hospital settings, operator roles should align with institutional bylaws and privileging standards. All operators should receive documented training and maintain competency through continuing education.

## 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.<sup>20</sup> 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 thetaburst 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.<sup>21</sup>

#### Depression

In 2022, the NICE published guidance addressing transcranial direct magnetic stimulation for the treatment of depression. <sup>22</sup> Investigators made the following recommendations:

- The evidence on repetitive transcranial magnetic stimulation (rTMS) for depression indicates no major safety concerns. Short-term efficacy is considered adequate, though clinical response may vary. rTMS may be used with standard arrangements for clinical governance, consent, and audit.
- Clinicians should ensure patients are informed about alternative treatment options and understand that rTMS may not result in clinical benefit. This discussion should be part of the consent process.
- NICE encourages further research and publication of evidence on optimal patient selection, stimulation protocols, 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.

# **HEALTH EQUITY CONSIDERATIONS**

The Centers for Disease Control and Prevention (CDC) defines health equity as the state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving health equity requires addressing health disparities and social determinants of health. A health disparity is the occurrence of diseases at greater levels among certain population groups more than among others. Health disparities are linked to social determinants of health which are non-medical factors that influence health outcomes such as the conditions in which people are born, grow, work, live, age, and the wider set of forces and systems shaping the conditions of daily life. Social determinants of health include unequal access to health care, lack of education, poverty, stigma, and racism.

The U.S. Department of Health and Human Services Office of Minority Health calls out unique areas where health disparities are noted based on race and ethnicity. Providence Health Plan (PHP) regularly reviews these areas of opportunity to see if any changes can be made to our medical or pharmacy policies to support our members obtaining their highest level of health. Upon review, PHP creates a Coverage Recommendation (CORE) form detailing which groups are impacted by the disparity, the research surrounding the disparity, and recommendations from professional organizations. PHP Health Equity COREs are updated regularly and can be found online here.

# **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*		
СРТ	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

08	891T	Accelerated, repetitive high-dose functional connectivity MRI–guided theta- burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0	892T	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
90	0867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90	0868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90	0869	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 <u>Medical Policy</u>, <u>Reimbursement Policy</u>, <u>Pharmacy Policy and Provider Information website</u> 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.
12/2025	Annual update. Updated age range to include 15-18 and added criteria for OCD.