HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Transcranial Magnetic Stimulation-Repetitive (rTMS)

Related Policies:
Admin-020 Noncovered Behavioral Health-Related Services

Policy MP-001

Origination Date: 04/09/2018

Reviewed/Revised Date: 05/23/2023

Next Review Date: 05/23/2024

Current Effective Date: 07/23/2023

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Transcranial magnetic stimulation (TMS) is a non-invasive method of induction of a focal current in the brain and transient modulation of the function of the targeted cerebral cortex. This procedure entails placement of an electromagnetic coil on the scalp; high-intensity electrical current is rapidly turned on and off in the coil through the discharge of capacitors. Depending on stimulation parameters (frequency, intensity, pulse duration, stimulation site), repetitive TMS (rTMS) to specific cortical regions can either increase or decrease the excitability of the affected brain structures.

Transcranial magnetic stimulation has been investigated in the treatment of various psychiatric disorders, especially depression. This procedure is usually carried out in an outpatient setting. In contrast to electroconvulsive therapy, TMS does not require anesthesia or analgesia. Furthermore, it does not affect memory and usually does not cause seizures. However, the available peer-reviewed medical literature has not established the effectiveness of rTMS in the treatment of psychiatric disorders other than major depression. In addition, more research is needed to ascertain the roles of various stimulation parameters of rTMS for its optimal outcome as well as its long-term effectiveness in the treatment of psychiatric disorders.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans covers repetitive transcranial magnetic stimulation when the following criteria for Initial Coverage is met (must meet ALL):

A. Patient is 18 years of age or older;

B. Treatment is provided by or under the direct supervision of a licensed psychiatrist or Psychiatric Advanced Practice Registered Nurse (APRN);

C. TMS device is FDA approved;

D. Request is for unilateral repetitive Transcranial Magnetic Stimulation (rTMS);

E. Diagnosis of major depressive disorder without psychosis (that meets the DSM-V definition*) by a licensed mental health professional, (Psychiatrist or APRN);

F. Failure of Medication Therapy defined by one of the following:

   i. Documented failure of at least 4 psychopharmacologic agent trials of adequate dose and duration (>4 weeks) from two different agent classes in the current episode;

   ii. Written documentation of an inability to tolerate psychopharmacologic agents as evidenced by four or more lifetime trials with distinctive side effects.

G. Member has no contraindications to rTMS such as:

   i. Seizure disorder/epilepsy;

   ii. No vagus nerve stimulator leads in carotid sheath;

   iii. No Conductive, ferromagnetic or other magnetic-sensitive metals implanted or embedded in the head within 30 cm of the TMS coil placement other than dental fillings (examples include metal plates, cochlear or ocular implants, deep brain stimulators, vagus nerve stimulator, staples, stents, etc.);

   iv. Neurological conditions (e.g., dementia, primary/secondary tumor in the central nervous system, cerebrovascular disease, history of repetitive/severe head trauma, or increased intracranial pressure);

   v. High alcohol or illicit drug consumption;

   vi. Acute or Active suicidal ideations; or

   vii. Acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in current depressive episode.

Maximum number of therapy sessions to be approved is 36 within an 8 week time period.

Criteria for repeat coverage:

A. Patient has previously undergone full course of rTMS and had a positive response defined by the use of appropriate standardized scales with testing dates of service;

B. Request ≥ 6 months since previous treatment.

**DSM-V definition of major depressive disorder (Please click on the following pdf):*

MDD Diagnostic Criteria.pdf

U of U Health Plans does NOT cover unilateral repetitive transcranial magnetic stimulation for any other behavioral health indication as it is considered investigational.

U of U Health Plans does NOT cover bilateral repetitive transcranial magnetic stimulation for any behavioral health condition as it is unproven and considered investigational.

U of U Health Plans does NOT cover navigated transcranial magnetic stimulation as it is considered experimental/investigational for motor function mapping and/or treatment planning of neurological diseases/disorders because its value and effectiveness has not been established.

U of U Health Plans does NOT cover accelerated repetitive transcranial magnetic stimulation for any behavioral health condition as efficacy has not been established, therefore it is considered investigational.

U of U Health Plans does NOT cover maintenance repetitive transcranial magnetic stimulation for the prevention of recurring depression symptoms as there insufficient evidence to establish safety and efficacy.

2. Medicaid Plans

As major depressive disorder is a carved out behavioral health condition for Traditional/Legacy Medicaid, this treatment is not covered by U of U Health Plans/Healthy U Medicaid.

U of U Health Plans/Healthy U Integrated Medicaid members are eligible for coverage based on the same criteria above as Commercial Plans.

Clinical Rationale

From the point of a systematic review perspective, In a Directory Report (Hayes 2016) on left repetitive high-frequency left transcranial magnetic stimulation (HFL-rTMS) for treatment-resistant depression, Hayes concluded that HFL-rTMS has a modest positive benefit, reducing the symptoms of depression, as a monotherapy and as an add-on therapy. According to Hayes, the quality of the large body of evidence was moderate, including 15 randomized, sham controlled trials (n=30–301). The evidence was insufficient to support HFL-rTMS for maintenance therapy to prevent relapse.

Another directory report on comparative effectiveness of HFL-rTMS (Hayes, 2016) reported that there was insufficient evidence to support the use of HFL-rTMS combined with ECT compared to ECT alone for treatment-resistant major depressive disorder. The conclusion was based on ten randomized controlled trials with small patient populations (n=32–121). Various outcome criteria and treatment regimens for rTMS and ECT were used.

Seven randomized controlled trials (n=26-170) were included from a technology brief (Hayes, 2016) on low frequency rTMS (LFrTMS) (1 Hz). The studies reported that LFrTMS, in addition to pharmacotherapy, produced antidepressant effects. However, results were mixed suggesting no difference between LFrTMS and sham therapy as an adjuvant therapy to antidepressant treatment. Results also suggested that there was no difference between LFrTMS and HFrTMS as an add-on therapy. The low-quality evidence did not allow definitive conclusions regarding the efficacy of LFrTMS as a monotherapy. The therapies appeared safe with mild adverse events (e.g., scalp discomfort, transitory headaches).

Currently, there are no standard protocols or expert consensus guidelines regarding the best approach to sustain a clinical response with TMS treatment. Definitions of the phases of treatment (e.g., acute, continuation, and maintenance) utilized for psychiatric treatments have been challenging to delineate in TMS research efforts and clinical practice. There is also inconsistent use of terms regarding long-term treatment, including maintenance, continuation, relapse prevention, and rescue treatment. (Williams et al., Chang et al.)

In a search and summary report on navigated Transcranial Magnetic Stimulation (nTMS) (Hayes, 2016), reported that although there was a moderate amount of published evidence, well-designed, large randomized controlled trials are lacking. A review of the abstracts showed conflicting findings. There was considerable overlap of authorship in the retrieved abstracts, and the majority of the published studies consisted of small patient populations with various diagnosis.

Hayes conducted a report in 2022 regarding accelerated repetitive transcranial magnetic stimulation (ArTMS) for the treatment of depression. Unlike conventional rTMS, which administers single daily sessions of stimulation across many weeks, accelerated rTMS delivers multiple sessions a day for just a few days (e.g., 15 to 20 sessions across 2 to 4 days). A search of the published peer-reviewed literature identified 3 clinical study abstracts and 3 systematic reviews/meta-analyses evaluating ArTMS for the treatment of depression. Clinical study abstracts included 2 randomized controlled trials (RCTs) and 1 comparative study. Comparators included standard rTMS (2 studies), sham treatment (1 study), and twice daily 10-day versus 15-day accelerated rTMS (1 study). The authors found that a formal review of the studies in a full appraisal may be warranted to draw conclusions regarding the quality and strength of the data. However, determining if a full appraisal will be conducted depends on whether ArTMS is emerging, evolving, controversial, or disruptive and the degree to which it is a priority to clients.

In March of 2023 Hayes conducted a health technology assessment for the use of repetitive transcranial magnetic stimulation (rTMS) for treatment of bipolar disorder (BD). The literature search identified 7 clinical studies that met inclusion criteria. Across the 7 studies, the mean age of enrolled patients ranged from 27.4 to 49.7 years and 14.3% to 69.2% were female. The average duration of the current BD

episode varied widely across the 3 reporting studies (49.5 days to 3.5 years). Similarly, 3 studies also reported a wide range of mean duration since BD diagnosis (47 months to 22.6 years). Most studies enrolled patients in a current depressive episode. One study included patients in a depressed or mixed state, but patients had to have moderate/severe depression symptoms to be enrolled in the study; 1 study enrolled patients with current mania. In general, patients had moderate/severe BD symptoms. Overall, the authors found insufficient evidence to draw conclusions regarding the efficacy and safety of rTMS for BD at this time.

Hayes conducted another tech assessment in April of 2023 regarding maintenance repetitive transcranial magnetic stimulation (rTMS) as a treatment to prevent the recurrence of symptoms in adult patients with major depressive disorder (MDD). A literature search identified 6 relevant clinical studies that met inclusion criteria. The studies included 17 to 281 patients with a mean age of 40.0 to 58.1 years and a mean duration of MDD ranging from 10.2 months to 20.5 years at study enrollment. The percentage of male patients ranged from 13% to 52.5% across studies. Two studies included a subset of patients (< 25%) who were diagnosed with bipolar disorder. In general, studies included patients who had responded to prior rTMS or pharmacological treatment with a reduction of depression symptoms and had previously completed an acute phase of rTMS (lasting 2 weeks to 6 weeks). The parameters for rTMS stimulation varied considerably across all studies and the majority of studies had notable heterogeneity in rTMS devices and protocols, small sample sizes, lacked power analyses, and had high rates of attrition. None of the studies compared rTMS with psychotherapy, electroconvulsive therapy (ECT), or other brain stimulation therapies. The authors concluded that current evidence suggests that rTMS is not more effective than sham treatment for the treatment of MDD. Therefore, further more robust comparative studies with larger sample sizes is necessary to address these shortcomings and to allow for reliable conclusions to be made.

The American Psychiatric Association practice guideline on major depression (2010, reaffirmed 2015) stated: "For patients whose symptoms have not responded adequately to medication, ECT remains the most effective form of therapy and should be considered. In patients capable of adhering to dietary and medication restrictions, an additional option is changing to a nonselective MAOI after allowing sufficient time between medications to avoid deleterious interactions. Transdermal selegiline, a relatively selective MAO B inhibitor with fewer dietary and medication restrictions, or transcranial magnetic stimulation could also be considered. Based on the results of a multisite randomized sham-controlled clinical trial of high-frequency TMS over the left dorsolateral prefrontal cortex (DLPFC), TMS was cleared by the FDA in 2008 for use in individuals with major depressive disorder who have not had a satisfactory response to at least one antidepressant trial in the current episode of illness. However, another large randomized sham-controlled trial of TMS added to antidepressant pharmacotherapy showed no significant benefit of left DLPFC TMS. In comparisons of actual TMS versus sham TMS, most but not all recent meta-analyses have found relatively small to moderate benefits of TMS in terms of clinical response. Although the primary studies used in these meta-analyses are highly overlapping and the variability in TMS stimulus parameters and treat treatment paradigms complicates the interpretation of research findings, these meta-analyses also support the use of high-frequency TMS over the left DLPFC. Lesser degrees of treatment resistance may be associated with a better acute response to TMS. In comparison with ECT, TMS has been found in randomized studies to be either less effective than ECT or comparable in efficacy to ECT, but in the latter studies TMS was more effective and ECT was less effective than is typically seen in clinical trials. A fewer number of studies have compared cognitive effects of TMS and ECT. One randomized trial found no significant difference between TMS and non-dominant unilateral ECT on performance on neuropsychological tests at 2 and at 4 weeks of treatment, although a small open-label trial reported a greater degree of memory difficulties with ECT than with TMS shortly after the treatment course."

In addition, the National Institute for Health and Care Excellence (NICE) issued an interventional procedural guidance document on TMS for treating and preventing migraines (January 2014). The authors reported that the evidence on the efficacy of TMS for the treatment of migraine and prevention of migraine is limited. Evidence on its safety in the short and medium term is adequate but there is uncertainty about the safety of long-term or frequent use of TMS. Nice concluded that the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

NICE also concluded in 2015 that the evidence on repetitive transcranial magnetic stimulation for depression shows no major safety concerns, and that the evidence on its efficacy in the short-term is adequate, although the clinical response is variable (NICE, 2015). The assessment found little data on the efficacy in the long-term and 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. The assessment also cited the need for 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.

Further, an assessment by the University of Calgary Health Technology Assessment Unit (Leggett et al., 2014) stated that, in adults with TRD, rTMS is more effective than no treatment but the optimal protocol remains unclear. The assessment found that few studies have reported on the effectiveness of rTMS compared to ECT. The assessment stated that pooled estimates for response and remission provide conflicting results indicating rTMS may be more effective at achieving response but less effective at achieving remission. The assessment concluded that the effectiveness of rTMS compared to ECT remains unclear. The assessment also concluded that the effectiveness in youth and young adult populations is uncertain.

From the published literature a systematic review by Leggett et al. in 2015 was performed to evaluate rTMS for treatment-resistant depression in young people, ages 13–25 years. Three prospective cohort studies with small patient populations (n=7–9) met inclusion criteria. Follow-ups ranged from one month to three years. Anxiety levels based on the Screen for Child Anxiety-Related Disorders Questionnaire were significantly lower but no significant difference was reported in the Suicide Ideation Questionnaire. The three-year study was a follow-up of an earlier study and suggested that the subjects did not experience worsening or improvement in depression severity over time without repeat rTMS. The third study reported a decrease in the mean Children's Depression Rating Scale. Meta-analysis was not possible due to the limited data. The limited number and the low quality of the studies restrict the ability to draw generalized conclusions about the use of rTMS in this age group. The rTMS protocols were heterogeneous. Currently, FDA approved TMS devices are only approved for use in adult patients, age 18 years and older.

Several variations of administering repetitive TMS to patients with major depression have been studied including: accelerated repetitive TMS, high-dose repetitive TMS, theta-burst repetitive TMS, deep-repetitive TMS, low frequency rTMS (LFrTMS) (1 Hz) and bilateral repetitive TMS (Holtzheimer et.al, 2015). A recent review of the evidence for TMS treatment of depression states that studies are being conducted to test a weak oscillating TMS device that is proposed to not cause seizures and therefore might enable home delivery of TMS for the treatment of schizophrenia and depression (George, et al., 2013). Currently, TMS is not recommended for use in the home nor are the devices FDA approved for in-home use.

The long-term effectiveness of TMS in naturalistic clinical practice settings was also evaluated following acute treatment for patients not benefiting from antidepressants (Dunner et al., 2014). Adult patients with a primary diagnosis of unipolar, non-psychotic major depressive disorder (DSM-IV clinical criteria), who did not benefit from antidepressant medication, received TMS treatment in 42 clinical practices. A

total of 257 patients completed a course of acute TMS treatment and consented to follow-up over 52 weeks. Assessments were obtained at 3, 6, 9, and 12 months. The study was conducted between March 2010 and August 2012. Compared with pre-TMS baseline, there was a statistically significant reduction in mean total scores on the Clinical Global Impressions-Severity of Illness scale (primary outcome), 9-Item Patient Health Questionnaire, and Inventory of Depressive Symptoms-Self Report (IDS-SR) at the end of acute treatment (all $p < 0.0001$), which was sustained throughout follow-up (all $p < 0.0001$). The proportion of patients who achieved remission at the conclusion of acute treatment remained similar at conclusion of the long-term follow-up. Among 120 patients who met IDS-SR response or remission criteria at the end of acute treatment, 75 (62.5 %) continued to meet response criteria throughout long-term follow-up. After the first month, when the majority of acute TMS tapering was completed, 93 patients (36.2 %) received re-introduction of TMS. In this group, the mean (SD) number of TMS treatment days was 16.2 (21.1). The authors concluded that TMS demonstrated a statistically and clinically meaningful durability of acute benefit over 12 months of follow-up. This was observed under a pragmatic regimen of continuation antidepressant medication and access to TMS retreatment for symptom recurrence. The main drawbacks of this study were: (i) its observational, naturalistic design (no concurrent control group), (ii) conclusions regarding the influence of concomitant treatments, including the role of TMS re-introduction, cannot be fully explored, and (iii) analysis using an LOCF (last-observation-carried-forward) analysis method may exaggerate the consistency of the scores.

Regarding maintenance treatment, continued treatment of depressive disorders after initial treatment response is necessary. However, there is limited evidence supporting continued use of rTMS after an initial treatment course to maintain the benefits of the initial course. A study evaluating maintenance rTMS compared to observation and reintroduction of rTMS upon worsening of symptoms showed no differences between approaches (Philip et al., 2016). A manufacturer-sponsored study of continuation rTMS after an index course compared to sham found no difference in remission rates between groups (Levkovitz et.al, 2015). Evidence that rTMS is superior to other antidepressant approaches, such as continued pharmacotherapy or psychotherapeutic treatments, after an initial course is also lacking.

A large multi-center cohort examined the safety and tolerability of navigated Transcranial Magnetic Stimulation (nTMS) in neurosurgical patients (Tarapore et. al., 2016). Functional mapping with monopulse and repetitive nTMS was performed in 733 patients. In this cohort, 57% of patients had left-sided tumors, 50% had frontal tumors, and 50% had seizures secondary to the lesion. Side effects and pain intensity related to the procedure were documented. Patients undergoing monopulse stimulation underwent an average of 490 pulses while those undergoing repetitive stimulation received an average of 2268 pulses. During monopulse stimulation, 5.1% reported discomfort, and 0.4% reported pain. During repetitive stimulation, 23.4% reported discomfort and 69.5% reported pain. No seizures or other adverse events were observed. The authors concluded that nTMS is safe and well-tolerated in neurosurgical patients. Clinicians should consider expanding nTMS to patients with frequent seizures, but more evaluation is necessary to evaluate this risk fully. Additional studies are needed to determine if nTMS improves patient outcomes.

In comparison with ECT, TMS has been found in randomized studies to be either less effective than ECT or comparable in efficacy to ECT, but in the latter studies TMS was more effective and ECT was less effective than is typically seen in clinical trials. A fewer number of studies have compared cognitive effects of TMS and ECT. One randomized trial found no significant difference between TMS and non-dominant unilateral ECT on performance on neuropsychological tests at 2 and at 4 weeks of treatment, although a small open-label trial reported a greater degree of memory difficulties with ECT than with TMS shortly after the treatment course. A meta-analysis of studies of ECT and TMS found that ECT had the greatest effect in depression, but that rTMS was better tolerated. (Chen et al., 2017). There is a lack of evidence using sham-controlled studies comparing rTMS to ECT. Additionally, rTMS has not been

shown to be effective in cases of depression with comorbid psychotic symptoms whereas this is a frequent indication for ECT.

Several sham-controlled studies were reviewed by Lefaucheur (2020) regarding the use of rTMS in patients with OCD. A positive randomized, controlled study (Carmi et al., 2019) evaluated high frequency rTMS to the medial prefrontal cortex along after symptom provocation and found significant reductions in Y-BOCS scores compared to the sham group. A number of other studies evaluating different approaches and targeting locations yielded negative results. Evidence of the benefit of other rTMS protocols in OCD is lacking, and no published data compares rTMS to other FDA-approved pharmacological or behavioral therapies for OCD.

Lefaucheur et al (2020), also reviewed rTMS procedures involving stimulation of the bilateral prefrontal cortex have been compared to unilateral procedures in patients with major depression. Results of direct comparisons have been mixed without clear support for bilateral approaches. In twelve studies reviewed only one reported superior results for bilateral rTMS over unilateral rTMS compared to a sham procedure.

Navigated rTMS refers to a modification to the targeting method that is suggested to be more anatomically accurate in localizing the dorsolateral prefrontal cortex (DLPFC) than the standard procedure of targeting the DLPFC. The standard procedure was used in the rTMS approval studies. There have been studies suggesting that the standard procedure was anatomically incorrect and suggesting that navigation may improve the accuracy of coil placement. Some case studies suggested a superior outcome when using navigated rTMS as compared to the standard procedure; other workers have proposed an alternative, non-navigated targeting procedure. In a literature review, (Lefaucheur, 2020) found that the hypothesis that navigated TMS improved the response compared to standard targeting had not been confirmed by large clinical trials.

Applicable Coding

CPT Codes

Covered codes if criteria are met:

90867 Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management

90868 ; subsequent delivery and management, per session

90869 ; subsequent motor threshold re-determination with delivery and management

Non-covered codes:

0858T Externally applied transcranial magnetic stimulation with concomitant measurement of evoked cortical potentials with automated report ***(New code as of 01/01/2024)***

HCPCS Codes

No applicable codes

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