Lucet™

Medical Policy Name	Transcranial Magnetic Stimulation for the Treatment of Major Depression for Florida Blue
Medial Policy Number	20.5.008
Issued By	Chief Medical Officer
Approved By	Medical Directors, Provider Advisory Committee, Corporate Quality Improvement Committee
Original Effective Date	02/2025

Applies To: 02/27/2025 to 12-31-2025

Description of Treatment

Transcranial magnetic stimulation (TMS) is a treatment technique that uses a magnetic field to influence brain activity. It is noninvasive and can help when other treatment approaches are not effective. The side effects are usually mild and temporary.

When Services May Be Eligible for Coverage

Coverage for eligible treatments or procedures may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Criteria

A. Expectations of Care Delivery
   1. Training and Requirements
      a. Lucet will register any clinics or practitioners via documentation of certification, prior to allowing use of this benefit.
      b. Psychiatrist
         i. Board-certified psychiatrist with training in the use of TMS for Major Depression.
         ii. Required to personally perform first TMS treatment (including cortical mapping, motor threshold determination, delivery, and management) and re-determination of the Motor Threshold (MT).
         iii. Subsequent TMS treatment may be administered by a psychiatrist.
      c. TMS Technician
         i. Required to have certification in administering TMS.
         ii. Subsequent TMS treatment may be administered by a technician.
   2. TMS administered with an FDA-approved or cleared device.

3. One (1) treatment session per day is given for five (5) consecutive days per week for six (6) consecutive weeks. Immediately following the six (6) (week treatment period, the treatment frequency is tapered, as follows:
    a. Week One (after six-week initial treatment): 3 treatment sessions
    b. Week Two (after six-week initial treatment): 2 treatment sessions
    c. Week Three (after six-week initial treatment): 1 treatment session
4. Standardized depression rating scales (Table 1) will be administered during TMS treatment to monitor progress at a minimal frequency of an initial pre-treatment test which is to occur prior to the six (6) week initial treatment period, followed by testing every two (2) weeks during the six (6) week treatment period and a final test at the last treatment visit. If the rating scales document a lack of meaningful change or worsening of symptom intensity, review by a physician advisor may be indicated.
    a. For consistency, one (1) rating scale should be chosen and administered during the entire treatment course.

Table 1 - Clinically Accepted Depression Rating Scales include but are not limited to:

Name	**Number of items**	**Minimum score for initial authorization**
Beck Depression Inventory (BDI)	21	>29
Inventory of Depressive Symptomatology Clinician-rated (IDS-C)	30	>36
Quick Inventory of Depressive Symptomatology Self-reported (QIDS-SR)	16	>15
Montgomery-Asberg Depression Rating Scale (MADRS)	10	>34
Patient Health Questionnaire (PHQ9)	9	>19

B. Initial Authorization Request
1. TMS meets the definition of medical necessity for a treatment resistant major depressive disorder when **ALL of the following criteria (sections a-c) have been met**.
    a. Confirmed diagnosis of severe Major Depressive Disorder WITHOUT Psychosis (International Classification of Disease: ICD-9 codes 296.2x and 296.3X, and ICD -10 codes F32.x and F33.x).
        i. Severity documented by one (1) clinically accepted depression rating scale from Table 1.
    b. The request is for a member between the ages of 15 and 70.
    c. The member has any **one of the following**:

i. Failure of two (2) trials of psychopharmacologic agents approved by the FDA for treating Major Depressive Disorder. These must include:
    1) Medicine trials from at least two (2) different antidepressant classes (for example SSRI, SNRI, TCA, MAI-O, etc.)
ii. Inability to tolerate a therapeutic dose of medications as evidenced by two (2) trials of psychopharmacologic agents from at least two (2) different antidepressant classes with documented distinct intolerable side effects.
iii. TMS is judged by the provider to be a less invasive treatment option to ECT in the specific case or the member is not willing to consent to ECT.

C. Retreatment Requests for TMS
    1. **Must meet both (a) and (b):**
        a. Meets all requirements for initial TMS treatment (above)
        b. Repeat acute treatment for relapse of depressive symptoms is considered medically necessary when both (a) and (b) are met:
            i. There is documentation submitted that the member responded to prior treatments, specifically with a 50% or greater improvement in a standard rating scale for depressive symptoms (Table 1).
            ii. A minimum of ninety (90) days has elapsed since the termination of the prior TMS treatment course.

D. Authorization if Determined to be Medically Necessary
    1. Initial authorization:
        a. One (1) unit of 90867, 36 units of 90868, and one (1) unit of 90869.
        b. Requests for additional units of 90869 should be submitted with detailed clinical rationale.
    2. Retreatment Requests
        a. 36 units of 90868

E. Limitations of Coverage - The use of TMS with any of the following is considered not appropriate or medically necessary:
    1. There is evidence of:
        a. Actively abusing substances (Urine Drug Screen (UDS) confirmation may be required)).
        b. Active psychotic symptoms.
        c. Acute suicidal risk
        d. Catatonia
        e. Life-threating dysfunction in basic life needs

   f. Active neurologic disorder, including but not limited to encephalopathy, dementia from any cause, Parkinson's Disease, post-stroke syndromes, increased intracranial pressure or bleeding, cerebral aneurysm, A-V malformations, CSF shunts, implants in the CNS or head/neck, etc.
2. The request is for treatment of psychiatric diagnoses found in the DSM other than Treatment Resistant Depression.
3. The request is for treatment of OCD.
4. The member has non-removable metallic objects or implants in his/her head or neck regions.
5. The request is for Maintenance TMS Treatment.
6. The request is for Intermittent Theta Burst Stimulation (iTBS).
7. The request is for Magnetic Seizure Therapy (MST), which is using TMS to stimulate the induction of seizures, has been tried as an alternative to the electrical induction of seizures in electroconvulsive therapy (ECT).
8. The request is for Navigated Transcranial Magnetic Stimulation (nTMS) which uses a diagnostic tool to stimulate functional cortical areas at precise anatomical locations to induce measurable responses. This technology is being investigated to map functionally essential motor areas for diagnostic purposes and for treatment planning.

Summary of Evidence

For the 2025 TMS Summary of Evidence, Lucet Health has reviewed literature after 2021.Topics reviewed included, but were not limited to, accelerated TMS, FMRI aided TMS, Theta Burst TMS, TMS in members aged 15-18, TMS in members over age 70, TMS for other conditions (including OCD, PTSD, and Bipolar Disorder). Interpretation of the TMS literature is still challenging because of a lack of standardization of protocols, variable results, varying subject populations, small study sizes, varying definitions of improvement, and lack of blinded control groups in many studies. Lucet Health does not recommend any changes to the 2024 TMS policy for 2025.

Summary of Evidence Since 2021:

Two clinical practice guidelines (CPG) (Walter et al., 2023; McQuaid et al., 2022) recommend psychotherapy and/or pharmacotherapy as first-line treatment interventions for all age groups.

One CPG (McQuaid et al., 2022), for adult patients who have demonstrated partial or no response to two or more adequate pharmacologic treatment trials (sufficient length and adherence), suggested offering repetitive transcranial magnetic stimulation (rTMS) for treatment. The CPG also indicated that there is insufficient evidence to recommend for or against theta-burst stimulation for the treatment of MDD.

Another study (Dalhuisen et al., 2024) found that rTMS was more effective than pharmacological treatment in patients with moderately treatment-resistant depression. Furthermore, greater reductions in symptoms of anxiety and anhedonia were observed after treatment with rTMS, which supports ongoing research in this area. rTMS should be considered as a viable treatment option at an early stage of the treatment algorithm and may be more effective than antidepressant medication switch or augmentation.

Repetitive transcranial magnetic stimulation (TMS) is established as effective and FDA-approved for individuals with TRD (Treatment Resistive Depression), with accelerated theta-burst TMS also recently showing efficacy (McIntyre et al., 2023).

Deep TMS is a technique that penetrates deeper into cortical brain tissue. There are few recent high-quality articles on this method. One 2023 article (Tendler et al., 2023) was a naturalistic study without a control group. Also, in this study, only 67% of participants were severely depressed.

Stanford neuromodulation therapy (SNT, previously referred to as Stanford accelerated intelligent neuromodulation therapy, or SAINT), a high-dose iTBS protocol with functional-connectivity-guided targeting (navigated TMS), was more effective than sham stimulation for treatment-resistant depression. Further trials are needed to determine SNT's durability and to compare it with other treatments (Cole et al., 2022).

In a 2023 post-marketing study of maintenance TMS (d'Andrea et al., 2023), it was noted that the peak of recovery was often up to 5 months after treatment was completed. Some benefits of treatment did not appear until several months after acute treatment. 14 studies were included, none done in the past 4 years. Only 2 were of TMS that started after acute treatment. There was no agreed upon protocol.

In a 2023 review of TMS for Bipolar Disorder (Mutz, 2023), the author noted that there are few sham-controlled studies of TMS in Bipolar Disorder. Of the main three, one showed effect greater than sham in 2 weeks but not at 4 weeks. Another study of 49 patients did not separate from sham TMS. Another using intermittent theta-burst stimulation (iTBS) did not separate from sham. Therefore, the only positive evidence for TMS efficacy in Bipolar Affective Disorder are case reports and uncontrolled studies.

Shamabadi et al. (2023) reviewed eleven studies of Bipolar Depression (BD) and response to TMS treatment when combined with neuroimaging modalities (5 navigated TMS methods). The studies suggested that nTMS may have benefits. This study reviewed significant clinical implications of neuroimaging modalities for prognosis, treatment planning, and patient outcomes in patients with bipolar depression who received TMS. Due to limitations, rTMS in BD research needs to be further studied and results replicated.

A pilot study of 31 subjects published in 2024 (Aaronson, et al.) showed positive results for conventional TMS in Bipolar Depression, suggesting that more research may be indicated.

Lorentzen et al. (2022) synthesized literature in a systematic review and quantitative meta-analysis of double-blind randomized controlled trials of TMS in patients with schizophrenia. 57 studies with a total of 2633 participants that were included in the meta-analysis. TMS appears to be an efficacious treatment option for patients with schizophrenia suffering from negative symptoms, but the optimal TMS parameters are yet to be established. There was, however, substantial heterogeneity and high risk of bias among the included studies.

Meta-analysis of updated evidence (Gay et al., 2022) to assess overall rTMS efficacy on craving, differential effects between addiction types clustered into three groups (depressant (alcohol, cannabis, opiate), stimulant (nicotine, cocaine, methamphetamine), and behavioral addiction (gambling, eating disorder)), and stimulation settings. Studies on substance use, gambling, and eating disorders are included, with unrestricted stimulation settings. A total of 34 eligible studies were identified. Because of highly significant heterogeneity in primary results, a sensitivity analysis was performed on a remaining sample of 26 studies (30 units of analysis). Analyses performed using random effects model revealed a small effect size favoring active rTMS over shamTMS stimulation in the reduction in craving. We found a significant difference between addiction types, with a persistent small effect only for stimulant and behavioral groups. In these groups we found no difference between the different combinations of target and frequency of stimulation, but a significant correlation between number of sessions and craving reduction. In conclusion, efficacy of rTMS on craving in stimulant and behavioral addiction was highlighted, but recommendations on optimal stimulation settings and its clinical application await further research.

In a 2022 systematic review of TMS in children and adolescents (Sigrist et al., 2022), the review notes: “To date, two randomized controlled trials on TMS in adolescent depression have been studied, and the only large-scale randomized trial suggests TMS is not more effective than sham stimulation.” Our review of the literature did not show any new studies published after 2022. Another review (Qiu et al., 2023) noted, “Repetitive transcranial magnetic stimulation (rTMS) benefits adults with depression while its efficacy and safety in children and adolescents with major depressive disorder (MDD) remain unclear.” It also noted most studies did not have a sham control group.

One CPG for children and adolescents (Walter et al., 2023) did not recommend TMS but stated that it was one area for additional treatment research.

In March 2024 the FDA cleared the Neurostar TMS device as “indicated as an adjunct for the treatment of Major Depressive Disorder (MDD) in adolescent patients (age 15-21) (Croarkin et al., 2024).” This decision was made based on a research poster describing

a naturalistic study of 1169 subjects who received TMS for major depressive disorder. Initial PHQ-9 scores were as low as 10 and the average age was 19.2 years old. TMS treatment resulted in marked improvement in both depressive symptoms and anxiety in both adolescents and young adults. As a naturalistic study, there was no control group. The authors concluded that TMS treatment resulted in marked improvement in both depressive symptoms and anxiety in both adolescents and young adults.

Several articles have come out regarding use of TMS in a geriatric population.

- In a 2022 retrospective review of geriatric depression (Cappon et al., 2022), the study subjects included subjects as young as 50. Studies had varying results and within studies results were heterogeneous. The RCT's done were not large studies.
- A 2022 study (Blumberger, et al., 2022) compared bilateral theta-burst stimulation (TBS) to conventional TMS and found it to be non-inferior. There was more pain with TBS. The average age was 67 years old. Subjects were rated using the Montgomery-Asberg Depression Rating Scale. In the TMS group, average decrease in depression scores was 32%. In the TBS group, the decrease was 38.5%. 35% of this group went into remission.
- In another retrospective analysis (Almheiri et al., 2023), the oldest subject was 71, so it does not inform of any potential change to our current policy limit of age 70. The mean age was 66. It also noted that the usual way of doing rTMS, Left DLPFC treatment, had no effect, only bilateral TMS did. The author speculated that more effective protocols for geriatric patients might be developed in the future.

The current literature does not robustly support raising the policy age limit of age 70 for TMS authorization.

Riddle et al. (2022) discussed the methodological challenges of concurrent TMS and fMRI. Both Magnetic resonance imaging and TMS rely on magnetic fields and when used simultaneously one can interfere with the other. Efforts have been made to address the complex interaction of TMS and fMRI. However, few experimental studies to date have utilized concurrent TMS-fMRI. The slow growth of this methodology is most likely due to an incomplete understanding of how an operating TMS coil impacts the MRI signal and the resulting lack of consensus regarding the most effective setup and methods for addressing unwanted artifacts.

<u>Summary of Evidence Prior to and Including 2021:</u>

One study (Cuijpers et al., 2020) found that psychotherapy alone and pharmacotherapy alone were equally effective, and that combined treatment was more effective in achieving response at the end of treatment for chronic and treatment-resistant depression.

(Sonmez et al., 2019)

This systematic review and meta-analysis aimed to examine accelerated TMS (aTMS) studies for depressive disorders in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. Overall, the meta-analysis suggested that aTMS improves depressive symptom severity. In general, study methodologies were acceptable, but future efforts could enhance sham techniques and blinding.

(Carmi et al., 2018)
Deep TMS significantly improved OCD symptoms and may be considered as a potential intervention for patients who do not respond adequately to pharmacological and psychological interventions.

(Rapinesi et al., 2019)
Different brain stimulation techniques are promising as an add-on treatment of refractory OCD, although studies frequently reported inconsistent results. TMS, DBS, and tDCS (transcranial direct current stimulation) could possibly find some use with adequate testing, but their standard methodology still needs to be established.

(Shivakumar et al., 2019)
Reviewed about 27 studies. Some TMS studies reported consistently positive effects on symptom reduction. However, those studies are few in number and sample size was less when compared against other areas in a meta-analysis. Some studies had reported mixed results, and all the findings from those studies are limited by small sample sizes. Various researchers had attempted pooling data from different studies to overcome this limitation by conducting meta-analyses. All five meta-analyses had uniformly suggested that there is definite benefit of add-on rTMS in patients with resistant OCD. There is a pressing need to establish further support with large trials in both resistant and nonresistant OCD patients. In addition to evaluating the persistence of improvement induced by rTMS, longitudinal studies are essential to establish long term safety of this technique.

(Cirillo et al., 2019)
Our meta-analysis suggests that TMS may be an effective treatment for GAD and PTSD. Since few studies have evaluated TMS for Specific Phobia and Panic Disorder, few conclusions can be drawn.

(Roth et al., 2020)
Deep transcranial magnetic stimulation (dTMS) was shown to be safe and effective as a treatment alternative for OCD and recently received regulatory approvals. Data from one double-blind multicenter dTMS study found efficacy of this novel treatment in OCD patient who previously failed to respond to multiple medications and CBT. Limitations of this analysis included small sample size and the lack of controlled monitoring of prior pharmacological and psychotherapy treatments.

(Fineburg et al., 2020)

rTMS appears to be a promising intervention in treatment-resistant OCD. There is a pressing need for large replication studies and evaluation of long-term effects / maintenance protocols.

(Roth et al., 2021)
In real-world clinical practice, the majority of OCD patients benefitted from dTMS, and the onset of improvement usually occurs within 20 sessions. Extending the treatment course beyond 29 sessions results in continued reduction of OCD symptoms, raising the prospect of value for extended treatment protocols in non-responders.

In a review of maintenance TMS (Rachid F., 2018), schedules for maintenance were described as TMS every 2-4 weeks for many months or years. The review noted that well-designed controlled studies were needed.

Exceptions

Exceptions to this medical policy must be approved by Lucet Chief Medical Officer or their designee.

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Related Documents

GUIDES / HANDOUTS
None

FORMS
Transcranial Magnetic Stimulation (TMS) Request Form

Document History

Date	Action	By Whom	Summary
02/2025	New	Dr. J. Langlow	Florida Blue requires age to start at 15 years old.