Transcranial Magnetic Stimulation

Date of Origin: 7/24/2018 **Last Review Date: 10/23/2024** **Effective Date: 11/1/2024**

Dates Reviewed: 7/24/2018, 12/2019, 10/2020, 9/2021, 10/2022, 10/2023, 10/2024

Developed By: Medical Necessity Criteria Committee

I. Description

Transcranial magnetic stimulation (TMS), including repetitive transcranial magnetic stimulation (rTMS) and deep transcranial magnetic stimulation (dTMS), is a noninvasive method of delivering electrical stimulation to the brain. It uses a specifically designed magnetic coil that is placed in contact with the scalp to generate rapidly alternating magnetic fields and produces electrical stimulation of cortical neurons. The procedure takes approximately 20-40 minutes and is generally administered daily over a four-to-seven-week period. TMS can be performed in an office setting as it does not require anesthesia and does not induce a convulsion.

Imaging studies have shown a decrease in activity of the left dorsolateral prefrontal cortex (DLPFC) in depressed patients, and early studies suggested that high frequency (e.g., 5–10 Hz) TMS of the left DLPFC had antidepressant effects. The FDA approved TMS in October 2008 for use in the treatment of treatment-refractory major depressive disorder (TRD) based on the results of a multisite randomized controlled clinical trial. It has approved several transcranial magnetic stimulation (TMS) systems and devices including e.g., NeuroStar® TMS Therapy System (Neuronetics, Inc.), Brainsway Deep TMS System (Brainsway Ltd.), Magstim Rapid2 Therapy System (Magstim Company Limited), MagVita TMS Therapy System (Tonica Elektronik A/S)).

Scientific literature supports the safety and effectiveness of TMS in treating TRD. It is believed to be generally less effective than Electroconvulsive Therapy (ECT) but with a much more benign side-effect profile. Data do not show an advantage for either rTMS or dTMS compared with the other. A typical course of TMS is 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 TMS treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week (36 treatments total). The role of follow-up or maintenance treatment has not been established in the literature and there is not yet a generally accepted protocol for maintenance treatment. The only RCT to study maintenance treatment did not demonstrate a statistically significant difference between treatment and sham control. A meta-analysis published in 2019 looked at the results of “almost exclusively naturalistic and open-label studies” and found patients with some form of maintenance treatment fared better than those without; the study, however, had numerous limitations and called for well-designed RCTs to establish the role of maintenance treatment. While there is evidence that maintenance TMS can reduce relapse and, in some cases, can improve depressive symptoms further, there is a significant lack of evidence and expert agreement on maintenance protocols (see d'Andrea, et al. Journal of Personalized Medicine Apr. 2023 for a recent literature review). Due to the paucity of high-

quality evidence, maintenance TMS is generally considered to be experimental/investigational. Evidence suggests that patients who have responded to an initial round of TMS and subsequently relapse may benefit from reintroduction.

The NeuroStar TMS platform was cleared by the FDA in March of 2024 to treat Major Depressive Disorder in adolescents 15 years of age or older. A data set of 169K treated patients (as yet unpublished) from Neurostar claimed a 78% response rate and a 48% remission rate. The criteria used was for patients with any level of depression after one failed medication trial.

Other indications: TMS has shown promise in the treatment of other conditions such as obsessive-compulsive disorder (OCD) and depression in bipolar disorder. The FDA permitted the marketing of The Brainsway Deep Transcranial Magnetic Stimulation System in August 2018 for the treatment of OCD. The permission was granted through the "de novo premarket review pathway," largely based on a multicenter trial by Carmi, et. al which was published in 2019. There is promising evidence for the effectiveness of the Brainsway device for OCD but its role has not been clearly established. Other literature (Carmi et. al., 2017; Trevizol, et. al., 2016) has provided evidence for the effectiveness of TMS for OCD and calls for additional research. Although Medicare currently limits coverage to treatment of TRD, the evidence for effectiveness in OCD appears strong enough at this point to support its use in some cases when standard OCD treatments have not been effective.

The following criteria are intended as a guide for establishing medical necessity for the requested level of care. They are not a substitute for clinical judgment and should be applied by appropriately trained clinicians giving consideration to the unique circumstances of each patient, including co-morbidities, safety and supportiveness of the patient's environment, and individual patients' unique needs and vulnerabilities.

II. Criteria: CWQI BHC-0014

A. Initiation Criteria:

Authorization for Initiation of Transcranial magnetic stimulation (TMS) is indicated by **ALL** of the following:

1) The device has FDA approval for the intended use.
2) The patient is age 15 or older for treatment of depression; age 18 or older for treatment of OCD.
3) The treatment meets **ONE** of the following indications:
    a) A confirmed diagnosis of treatment-resistant severe major depressive disorder (single episode or recurrent) demonstrated by **ALL** of the following:
        (i) Results of a standardized evidence-based depression rating scale that reliably measures depressive symptoms.
        (ii) Identification of the onset of the current episode and history of any previous episodes.
        (iii) Differential diagnosis has been completed and another diagnosis such as depressive disorder due to another medical condition does not better account for the patient's symptoms.

(iv) The patient has had adequate trials of pharmacological treatments with less than a 50% reduction in symptoms as documented on a standardized measurement tool, including **ALL** of the following:
1. At least two different antidepressant agents (concurrently or separately) with adequate dose and duration (or discontinued due to intolerable side-effects)
2. At least six weeks' duration for one or more of the antidepressant agents (unless none of the agents was tolerated); and
3. Documentation of the drug trials includes description of doses, duration, side-effects, augmentations and response.

(v) The patient has had an adequate trial of an evidenced based psychotherapy within the current depressive episode including **ALL** of the following:
1. Description of modality, frequency, duration;
2. Documentation of inadequate response. This should generally include documentation of less than a 50% reduction in symptoms using a standardized measurement tool; OR

b) A confirmed diagnosis of treatment-resistant severe obsessive-compulsive disorder as evidenced by **ALL** of the following:
(i) Results of a standardized evidence-based OCD rating scale
(ii) Description of symptomatology and relevant history
(iii) The patient has had adequate trials of pharmacological treatments with less than a 30% reduction in symptoms as documented on a standardized measurement tool, including **ALL** of the following:
1. At least two different agents (concurrently or separately) with adequate dose and duration (or discontinued due to intolerable side-effects)
2. At least six weeks' duration for one or more of the agents (unless none of the agents was tolerated); and

(iv) Documentation of the drug trials includes description of doses, duration, side-effects, augmentations and response.
(v) The patient has had an adequate trial of Exposure and Response Prevention (ERP) therapy including **ALL** of the following:
1. Description of modality, frequency, duration;
2. Documentation of inadequate response. This should generally include documentation of less than a 30% reduction in symptoms using a standardized measurement tool; AND

4) Treating provider has ruled out the presence of contraindications such as active substance use disorder, seizure disorder, or any medications, implants or devices that may compromise the safety or efficacy of the procedure. The Transcranial Magnetic Stimulation Adult Safety Screen (TASS) is a specific questionnaire that may used to assess an individual's safety for TMS.

B. <u>Continued Care Criteria:</u>

Authorization extending a standard course of TMS beyond 36 sessions is indicated by **ALL** of the following:

1) The patient has shown a positive response to treatment as evidenced by a reduction in depressive symptoms on a standardized measurement tool.
2) Additional visits are needed due to a need for re-mapping or other confounding factors.
3) The treatment plan includes a plan for completing treatment with the lowest appropriate number of additional sessions.

C. Reintroduction Criteria:

Authorization for reintroducing TMS after completion of an acute episode of treatment is indicated by **ALL** of the following:

1) Patient responded positively to previous course of TMS, as evidenced by a 50% or better improvement in depressive symptoms or 30% or better improvement in OCD symptoms as measured by a standardized instrument.
2) Sufficient time has elapsed since the completion of treatment to establish a clinically meaningful increase in symptoms
3) Patient's symptoms have worsened as evidence by a 50% or greater increase from peak response, measured by the same standardized instrument used in previous treatment.
4) Other treatment approaches (e.g., psychotherapy, pharmacotherapy, ERP) are employed concurrently as appropriate.

Guideline Note: Administration of standard symptom inventories such as the Y-BOCS, PHQ-9 or HAM-D is a routine component of assessment for appropriateness of TMS and response to treatment. Administration of these symptom inventories in this context is not psychological testing and may not be billed with CPT codes 96130-96139.

III. Information Required with the Prior Authorization Request:

A. Psychiatric evaluation including:
   1) Chart notes from the evaluation
   2) Diagnosis and symptomatology.
   3) Results of standardized evidence-based symptom rating scale.
   4) Relevant history including at a minimum:
      a) Onset of current episode and description of any previous episodes.
      b) Treatment history, including
         i) Psychotherapy or behavioral therapy: Dates, modality, frequency, duration, response.
         ii) Pharmacotherapy: Dates, medications, doses, side-effects, augmentations, response.
      c) Substance use history including sufficient detail to assess the potential impact of substance use on treatment.
   5) Documentation of screening for contraindications.
B. Requested CPT codes, units and date span.

IV. CPT or HCPC codes covered:

Codes	Description
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold redetermination with delivery and management.

V. Annual Review History

Review Date	Revisions	Effective Date
8/1/2018	New criteria	8/1/2018
12/2019	Annual review. Added references. Clarified required detail in psychiatric evaluation. Added evaluation of literature for OCD. Clarified requirements for augmentation trial.	1/1/2020
10/2020	Annual review. Added newer literature re: OCD. Simplified organization of requirements for pharmacotherapy and psychotherapy.	11/1/2020
9/2021	Annual review. Added requirement to rule out other disorders such as depression due to another medical condition. Updated requirements for retreatment. Clarified requirement for chart notes from the psychiatric evaluation. Updated LCD references.	10/2021
10/2022	Annual review. Reduced number of medication trials required in MDD. Added indication for OCD.	11/2022
10/2023	Annual review. No changes.	11/2023
10/2024	Annual review. Expanded information on maintenance TMS. Revised age requirement to 15+ for treatment of depression. Identified recommended safety screening. Cited additional studies for change to age requirement and maintenance TMS.	11/2024

VI. References

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VII. Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
F33.2	Major depressive disorder, Recurrent, Severe
F32.2	Major depressive disorder, Single episode, Severe
F42	Obsessive-compulsive disorder

VIII. Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
Noridian Healthcare Solutions, LLC: L37088	

NCD/LCD Document (s):
Repetitive Transcranial Magnetic Stimulation (rTMS) in Adults with Treatment Resistant Major Depressive Disorder (L37088)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC