Transcranial Magnetic Stimulation

Date of Origin: 7/24/2018 **Last Review Date: 10/28/2020** **Effective Date: 11/1/2020**

Dates Reviewed: 7/24/2018, 12/2019, 10/2020

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. 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. A meta-analysis published in 2019 looked at 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. Due to the paucity of high-quality evidence, maintenance TMS is often considered to be experimental/investigational. Given that TRD is a chronic condition, some patients with a positive response to TMS may benefit from reintroduction or some form of booster sessions. Clinical judgment with consideration of patient history and resources, response to treatment, and appropriateness of other treatments is necessary in order to weigh the appropriateness of additional treatment beyond the acute course.

The FDA permitted marketing of The Brainsway Deep Transcranial Magnetic Stimulation System in August, 2018 for treatment of obsessive compulsive disorder (OCD). The permission was granted through the "de novo premarket review pathway," largely on the basis of 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. Recent literature (Carmi et. al., 2017; Trevizol, et. al., 2016) has provided evidence for the effectiveness of TMS for OCD and calls for additional research. The meta-analysis by Trevizol, et. al., for example, concludes that "further phase III studies assessing broader samples are fundamentally needed to clarify the potential impact of TMS in the treatment of OCD symptoms in daily clinical practice." Medicare coverage remains limited to treatment of TRD. Independent confirmation of the results published in 2019 by Carmi, et. al may be sufficient to establish an indication for TMS for OCD.

II. Criteria: CWQI BHC-0014

A. Initiation Criteria:

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

1) Confirmed diagnosis of severe major depressive disorder (single episode or recurrent) demonstrated by **ALL** of the following:
    a) Results of a standardized evidence based depression rating scale that reliably measures depressive symptoms.
    b) Identification of the onset of the current episode and history of any previous episodes.
2) The patient is age 18 or older.
3) The patient has had adequate trials of pharmacological treatments with inadequate response documented on a standardized measurement tool, including **ALL** of the following:
    a) At least four different psychopharmacologic agents with adequate dose and duration (or discontinued due to intolerable side-effects)
    b) At least one adequate, evidence-based augmentation trial consistent with the community standard of care; and
    c) At least two different agent classes.
    d) Documentation of the drug trials includes description of doses, duration, side-effects, augmentations and response.
4) An adequate trial of an evidenced based psychotherapy within the current depressive episode, with description of modality, frequency, duration, and inadequate response; AND
5) 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.

B. Continued Care Criteria:

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. <u>Reintroduction Criteria:</u>

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

1) Clinical need for additional treatment is demonstrated by 1 or more of the following:
    a) Recurrence of symptoms meeting criteria for initial authorization of TMS; or
    b) Patient history demonstrating a substantial risk of deterioration that can't be prevented by other means such as pharmacological and/or psychotherapeutic intervention.
2) A reasonable expectation that additional treatment will produce clinical benefit
3) Other treatment approaches (e.g., psychotherapy, pharmacotherapy) are employed concurrently as appropriate; AND
4) Treatment is provided at the lowest number of sessions required to maintain/continue improvement.

III. Information Submitted with the Prior Authorization Request:

A. Psychiatric evaluation including:
    1) Diagnosis and symptomatology.
    2) Results of standardized evidence based depression rating scale.
    3) Relevant history including at a minimum:
        a) Onset of current depressive episode and description of any previous episodes.
        b) Treatment history, including
            i) Psychotherapy: 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.
    4) 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

VI. References

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US Food and Drug Administration (2018). FDA permits marketing of transcranial magnetic stimulation for treatment of obsessive-compulsive disorder. Retrieved 12/12/2019 at https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-transcranial-magnetic-stimulation-treatment-obsessive-compulsive-disorder

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

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):
Wisconsin Physicians Service Insurance Corporation: L34641	

NCD/LCD Document (s):
Transcranial Magnetic Stimulation (TMS) L34641

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