

Transcranial Magnetic Stimulation

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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.

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. As a result, maintenance TMS is considered by some 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 Food and Drug Administration (FDA) has approved several transcranial magnetic stimulation (TMS) systems and devices (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)).

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) documented by a standardized evidence based depression rating scale that reliably measures depressive symptoms.
2. The patient is age of 18 or older.
3. The patient has had adequate trials of other treatments with inadequate response documented on a standardized measurement tool, including **ALL** of the following:
 - a) Appropriate pharmacological treatment consisting of at least four different psychopharmacologic agents with adequate dose and duration (or discontinued due to intolerable side-effects) including
 - (1) At least one augmentation trial; and
 - (2) At least two different agent classes.
 - b) An adequate trial of an evidenced based psychotherapy within the current depressive episode; AND
4. Treating provider has ruled out the presence of contraindications such as active substance abuse, 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. Reintroduction Criteria:

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:

Psychiatric evaluation including diagnosis, symptomatology, results of standardized evidence based depression rating scale, treatment history (psychotherapeutic and pharmacologic), screening for contraindications and requested services.

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

VI. References

Avery DH et al. (2008). Transcranial Magnetic Stimulation in the Acute Treatment of Major Depressive Disorder: Clinical Response in an Open-Label Extension Trial. *J Clin Psychiatry* 69(3):441-451.

Connolly KR , Helmer A, Cristancho MA, Cristancho P, O'Reardon JP (2012). Effectiveness of transcranial magnetic stimulation in clinical practice post-FDA approval in the United States: results observed with the first 100 consecutive cases of depression at an academic medical center. *J Clin Psychiatry*. 73(4).

Dunner, DL, et al. (2014). A Multisite, Naturalistic, Observational Study of Transcranial Magnetic Stimulation for Patients With Pharmacoresistant Major Depressive Disorder: Durability of Benefit Over a 1-Year Follow-Up Period. *J Clin Psychiatry* 75(12):1394–1401.

Fitzgerald PB , Grace N, Hoy KE, Bailey M, Daskalakis ZJ, (2013). An open label trial of clustered maintenance rTMS for patients with refractory depression. *Brain Stimul*. 6(3):292-7.

George, MS et al. (2010). Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder: A Sham-Controlled Randomized Trial. Arch Gen Psychiatry. 67(5):507-516.

Kedzior KK , Reitz SK, Azorina V, Loo C. (2015). Durability of the antidepressant effect of the high-frequency repetitive transcranial magnetic stimulation (rTMS) In the absence of maintenance treatment in major depression: a systematic review and meta-analysis of 16 double-blind, randomized, sham-controlled trials. Depress Anxiety. 32(3):193-203.

Kelly, MS et al. (2017). Initial Response to Transcranial Magnetic Stimulation Treatment for Depression Predicts Subsequent Response. J Neuropsychiatry Clin Neurosci. 29(2): 179–182.

Levkovitz, Y et al. (2015). Efficacy and safety of deep transcranial magnetic stimulation for major depression: a prospective multicenter randomized controlled trial. World Psychiatry. 14:64–73.

O'Reardon JP , Blumner KH, Peshek AD, Pradilla RR, Pimiento PC (2005). Long-term maintenance therapy for major depressive disorder with rTMS. J Clin Psychiatry. 66(12):1524-8.

O'Reardon JP et al. (2007). Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multisite Randomized Controlled Trial. Biol Psychiatry. 62:1208-1216.

Richieri R et al. (2013). Maintenance transcranial magnetic stimulation reduces depression relapse: a propensity-adjusted analysis. J Affect Disord. 151(1):129-35.

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